ASSESMENT OF HEALTH RELATED QUALITY OF LIFE IN SUBJECTS WITH HYPERCHOLESTROLEMIA IN PRIVATE MEDICAL CENTRE

Dissertation submitted to

THE TAMILNADU Dr. M.G. R. MEDICAL UNIVERSITY, CHENNAI - 32

In partial fulfillment for the award of degree of

MASTER OF PHARMACY
IN
PHARMACY PRACTICE

Submitted By

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MAY – 2012

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This is to certify that the dissertation work entitled **"ASSESMENT OF HEALTH RELATED QUALITY OF LIFE IN SUBJECTS WITH HYPERCHOLESTROLEMIA IN PRIVATE MEDICAL CENTRE"**is the bonafide work carried out by Miss**. Anitha Marium Eapen**, Department of Pharmacy Practice, JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION, COLLEGE OF PHARMACY, Komarapalayam under my personal guidance and supervision.

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DECLARATION

I hereby declare that this dissertation entitled "**ASSESMENT OF HEALTH RELATED QUALITY OF LIFE SUBJECTS WITH HYPERCHOLESTROLEMIA IN PRIVATE MEDICAL CENTRE"** has been carried out by me under the guidance and supervision of Dr**. N. NANADHAKUMAR, M. Pharm., Ph.D., Professor** and under the Co-Guidance and supervision of **Mr.V.KISHOR KUMAR,M.Pharm.,Ph.D.,**Department of Pharmacy Practice, JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION, COLLEGE OF PHARMACY, Komarapalayam in a partial fulfillment of requirements for the Degree of Master of Pharmacy In Pharmacy Practice.

I further declare that this work has not been submitted earlier in part of full for the award of any degree or diploma to this or any other University.

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ACKNOWLEDGMENT

At this juncture, I would like to thank my **PARENTS** for their affection and perseverant, benevolence throughout our education and submit our sincere thanks to our teachers who reformed us from our early days of education to our graduation for moulding us as a professionals.

It is my great privilege, pride and honour in expressing my deepest sense of gratitude to my esteemed inspiring, untiring guide **Dr. N. NANADHAKUMAR M.Pharm., Ph.D.,** Professor, and Co- guide Mr. V. Kishore Kumar M.Pharm., Ph.D Department of Pharmacy Practice, JKKMMRF College of Pharmacy, Komarapalayam, in presenting this thesis entitled "**ASSESMENT OF HEALTH RELATED QUALITY OF LIFE IN SUBJECTS WITH HYPERCHOLESTROLEMIA IN PRIVATE MEDICAL CENTRE."** his constant inspiration, memorable guidance innovative ideas, instigation, at various stages and above all his untiring valuable support has brought out this thesis to great success.

It gives me an immense pleasure to convey all my respects and whole hearted gratitude to our honourable Principal **Dr. N. Senthilkumar**, **M. Pharm**., **Ph.D.,** JKKMMRF College of Pharmacy, Komarapalayam.

I show my regard to **Mr. K. G. Parthiben,M.Pharm,** Vice Principal, and JKKMMRF College of Pharmacy for his support towards this work.

I show my regard to **Mr. S. Kannan, M. Pharm.,**Professorand Head of Pharmacy Practice, JKKMMRF College of Pharmacy for his support towards this work.

I submit my sincere thanks and respectful regard to our beloved Managing Trustee, **Dr. JKK MUNIRAJAHH M.Tech (Bolton), D.Lit.,** for all the facilities that were provided to me at the institution enabling me to do the work of this magnitude.

It gives me an immense pleasure to convey all my respects and whole hearted gratitude to **Mr. K. C Arul Prakasam,M.Pharm.,**

I extend my sincere thanks to Teaching and Non-Teaching Staff Members of all the Departments of JKKMMRFCollege of Pharmacy for their timely suggestions, support and encouragement.

My special thanks to **Mr. Melbin John M.Sc. Biostatics and Mr. Tilu Thomas M.Sc. Biostatics** for their timely support.

This project would not be a resplendent one without the timely help and continuous support rendered by my ever loving friends of Department of Pharmacy Practice, and I take this opportunity to acknowledge them with thanks.

Above all I dedicate myself before the unfailing presence of **GOD.**

CONTENTS

INTRODUCTION

The prevalence of the disorder varies depending on the definition of dyslipidemia and the population studied. In patients with coronary heart disease (CHD), the prevalence of dyslipidemia is as high as 80% to 88%, compared to approximately 40% to 48% in age matched control without coronary disease. There is a strong correlation between BMI and incidence of hypercholestrolemia. The incidence is therefore higher in industrialized countries compared to developing countries.(Geneat J J Martin et al,1992)

A worrisome development is the increase in the rate of risk factors, in developing countries, for CHD (including hypercholesterolemia), while the risk factors for CHD decrease in prevalence in industrialized countries. However, while there has been a steady decline in mortality from heart disease in the US since the early 1960s, it still remains the leading causes of death for both men and women of all races and ethnicities.(Pearson T A et al,1999).

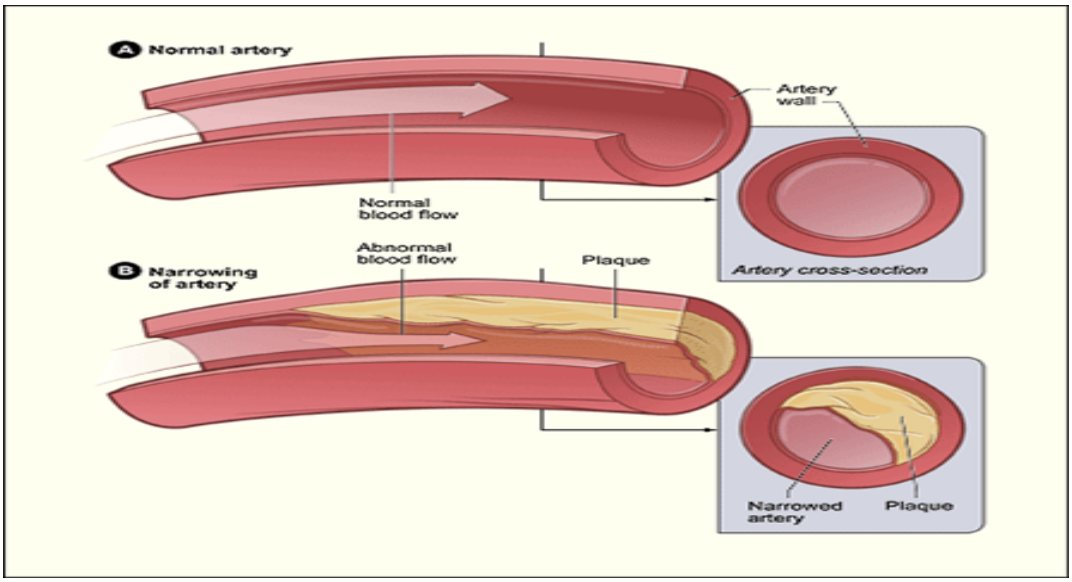
Lipid and lipoprotein concentrations vary among different populations, with countries consuming a western type of diet generally having total cholesterol and LDL-C levels than those where regular consumption of saturated fat is low.

The ideal plasma lipid profile is unknown and varies between different populations, even across Europe, and also within a given population. An relationship between total cholesterol and the development of coronary heart disease is recognized, as is its contribution to the 1 in 4 deaths from coronary heart disease that occurs each year in the U.K.A reduction in the mean level of cholesterol in the population will reduce the development of coronary atherosclerosis and the prevalence of coronary heart disease. In the individual there is little evidence of a level below which a further reduction of total cholesterol od LDL-C is not associated with a lower risk of coronary heart disease.

A population approach to screening for raised total cholesterol and LDL-C would be expensive to implement and must run in parallel with programmes that identify individuals with dyslipidemia and/or other risk factors for coronary heart disease. Some believe only individuals under the age of 20 years. (Joseph T Dipro,

Definition

Hypercholesterolemia, an elevation of total cholesterol (TL) and or LDL –cholesterol in the blood, is also often referred to as dyslipidemia, to encompass the fact that it might be accompanied by a decrease in HDL-cholesterol or an increase in triglycerides. Dyslipidemia is classified as serum TL, LDL-cholesterol, triglyceride, Apo lipoprotein B (Apo B) or lipoprotein (a) concentrations above 90th percentile, or HDL-cholesterol or Apo lipoprotein A-1 concentration below the 10th percentile for the general population. High cholesterol levels increase a person's chance of developing heart disease, particularly, coronary artery disease.



High levels of cholesterol in the blood result in the build up a plaque along the inner lining of the arteries. Over time, the build of up plaque leads to a narrowing and hardening of the arteries and a reduction in blood flow. This is called atherosclerosis. The presence of

atherosclerosis increases a person's risk of having a heart attack or stroke.(Farmer J A et al,1996).

Lowering cholesterol levels can slow down, reduce, or even stop plaque from building up in the arteries. This means, treating high cholesterol levels can reduce a patient,s chance of having a heart attack or stroke.

Treating high cholesterol, levels includes dietary changes, and the use of cholesterol-lowering medications. High blood cholesterol is also referred to as hypercholesterolemia. It is related to hyperlipidemia (elevated levels of lipids in the blood).

Cholesterol:

Cholesterol was a waxy fat-like substance that was found in all cells of the body and in some of the foods. Cholesterol was essential nutrient necessary for many functions including:

- Repairing the cell membranes.
- Manufacturing the vitamin D on skin's surface
- Producing hormones such as that estrogen, testosterone
- Possibly helping cell connections in brain that is an important for learning and memory.

Regardless these benefits when cholesterol levels rise the blood and that can have dangerous consequences depending on that type of the cholestrol and its production stimulated by saturated fat.

Triglycerides:

Triglycerides were composed of fatty acid molecules. The the basic chemicals contained in that fats in both animals and plants.

Characteristics Of The Major Classes Of Lipoproteins

Category	Composition	Origin
Chylomicrons	Exogenous/dietary triglycerides	Gut
Very-Low-Density-Lipoproteins(VLDLs)	Triglycerides	Liver
Intermediate-density lipoproteins	Cholesterol esters and Lipoproteins	VLDL/HDL Catabolism
Low density lipoproteins	Cholesterol	VLDL Catabolism
High-density lipoproteins (HDLs)	Cholesterol	Liver and Gut

Lipoproteins:

Lipoproteins are spheres that transport cholesterol, triglycerides, or other lipid molecules through in the blood stream. Most of that information about that effects of cholesterol and triglyceride actually concerns lipoproteins.

Lipoproteins were categorized into 5 types according to size and density and they can be further defined and by that whether they carry cholesterol/triglycerides.

- Cholesterol-carrying lipoproteins: These were the lipoproteins commonly referred to as cholesterol. Low density lipoprotein (LDL): (often called "bad "cholesterol).
- High Density Lipoprotein (HDL): the smallest and most dense.(often called "good "cholesterol.
  - ✓ Triglyceride-carrying lipoproteins.
- Intermediate density lipoproteins (IDL).They tends to carry triglycerides.

- Very low density lipoproteins (VLDL) .These tends to carry triglycerides.
- Chylomicrons is the largest in size and lowest in density.

Alternative Names:

- Lipid disorders,
- Hyperlipoproteinemia,
- Hyperlipidemia,
- Dyslipidemia,
- Hypercholesterolemia

Effects of lipoproteins and Triglycerides on heart disease.

Low Density Lipoprotein (LDL), the "Bad" cholesterol .The lowest incidence of the heart disease was usually found in among people who having the lowest low density lipoprotein levels, lowering LDL is the primary goal of cholesterol drub of the lifestyle therapy.

LDL transports about 75% of the blood's cholesterol to the body's cell's. It was normally harmless. However, if it was exposed to a process called oxidation, Low Density Lipoprotein can penetrate and interact with dangerously with in the walls of the artery that can producing a harmful inflammatory response. Oxidation was a natural process in the body that can occurs from chemical combination with unstable molecules. These molecules were known as oxygen-free radicals or oxidants.

High Density Lipoproteins (HDL), the "good" cholesterol:

High Density lipoprotein (HDL) appears to benefit in the body in two ways:

- Its removes the cholesterol in from the walls of the arteries, returns to the liver for disposal from body.

- It helps to prevent oxidation of Low Density Lipoprotein and High Density Lipoprotein actually appears to have its own antioxidants properties.
- It is might that fight inflammation.

HDL (high density lipoprotein) that helps to keep arteries open and reduce the risk for heart attack. High levels of high density lipoprotein (above 60mg/dl) may be nearly as protective for heart as the low levels of LDL.HDL levels below 40mg/dl are associated with in increased risk of heart disease.

Triglycerides:

Triglycerides interact with HDL (high density lipoprotein) cholesterol in such that way that high density lipoprotein levels that falls as triglyceride level rises and high triglycerides may pose other dangers regardless of cholesterol levels. For eg they can may be associated with the blood clot and that form then block the arteries.

High triglyceride, were levels also associated with that inflammatory response- -the harmful effect of overactive immune, system that can be considerable in that damage to cells, tissues and including the arteries.

Cholesterol, triglycerides goals

Total cholesterol count includes measurements of LDL (low desity lipoprotein), HDL, and triglycerides. The following in that chart summarizes in all lipid goals for all adults.

Cholesterol Goals For Adults

Total Cholesterol Goals	**LDL Goals**	**HDL Goals**	**Triglyceride Goals**
Less than 200 mg/dl is desirable	70 mg/dl is considered an	Levels above 40 mg/dl are desirable;	Below 150 mg/dl is normal.

	important goal in a very high-risk patients.	levels above 60 mg/dl are optimal	
Between 200 and 239 was a borderline.	Below 100 mg/dl was an optimal for everyone. It should be the goal for high-risk people including those with existing heart disease and diabetes and or two or more risk factors for heart disease; 70 mg/dl is an optimal goal for these individuals.		150-199 is borderline high
Over 240 is high			200-499 is high
			Over 500 is very high
	130 mg/dl or below for people with two or more risk factors; was 100 mg/dl is an optimal goal.		
	160 mg/dl ,below for		

	people at less risk factors; 130 mg/dl is an optimal goal.		
	Anything above 160 mg/dl is high, with levels above,190 being very high. LDL (loe density lipoprotein) levels over 190 require that medication even with no other cardiac risk factors.		

Risk factors for that heart disease include in a family history, of early heart problems before age 55 for men (before age 65 for women) and smoking, high blood pressure and diabetes, being older and were having high density lipoproetein) levels below 35mg/dl and People, with two or more of that risk factors may have a 10-year risk of the heart attack that can exceeds 20% and may therefore need that aim for LDL (low density lipoprotein) level of that 100 mg/dl or below.(Cuche I M et al,2007)

Classifications of Dyslipidemia

Dyslipidemia that can be the result of genetic predisposition secondary causes, or a combination of both. Cholesterol and triglycerides can produce the three forms of dyslipidemia: hypercholesterolemia, hypertriglyceridemia,that and a combination in both. In

each case that dyslipidemia were the result of an that elevation in that either that number or composition of the specific lipoproteins that which is an important determinant when selecting the appropriate drug therapy. Hypercholesterolemia, was associated with an increased concentration of one or more of the cholesterol-carrying lipoproteins (LDL, VLDL, HDL) which may can occur because of that higher concentration of cholesterol in each particle an increased number of particles and or a combination of both. Both, very low density lipoprotein and LDL particles that contain one lipoprotein B-100 molecule and therefore an elevation of that Apo lipoprotein B concentration reflects an increased in a number of that cholesterol-containing particles, which was associated with in hypercholesterolemia. Conversely the cholesterol content of that chylomicron particles was minimal and therefore an elevation in chylomicron concentrations, rarely causes hypercholesterolemia. Under normal situations approximately 70% to 80% of total cholesterol, that was can be found LDL particles.

The most of the common cause of hypercholesterolemia, was an elevation in LDL cholesterol. Yet the total cholesterol was the arithmetic sum of the cholesterol found in LDL, HDL, and VLDL particles. Therefore any one or that a combination of these particles may be responsible for that elevation. For example, hypercholesterolemia that can be occur because of that high HDL cholesterol although LDL and VLDL (very low density lipoprotein) concentrations was within acceptable concentrations.

One of the most, studied forms of dyslipidemia was familial hypercholesterolemia. These patients have to defective gene from one or both parents for the B-E/LDL receptor, significantly reducing their ability to clear LDL from the blood. Homozygous familial hypercholesterolemia, that can be result in

four to six times the normal concentration of cholesterol and significant atherosclerotic disease and detected during in the teenage years. Heterozygous familial hypercholesterolemia, were can cause two to four times in that normal concentrations of the cholesterol and with the premature atherosclerotic disease.

Polygenic hypercholesterolemia, that represent the largest group with approximately 36%, of the Americans diagnosed with in that forms of elevated cholesterol. These patients tend to have a number of defects the mostly related to nutritional and genetic factors resulting were a less active B-E/LDL receptor. Cholesterol levels, in these patients are approximately twice the normal levels.

Hypertriglyceridemia that can be occur in the patients with high concentrations of very low density lipoprotein or chylomicron particles. Most of the cases were mild and that are primarily caused by increased VLDL secretion by liver in patient that who consume an excessive amount of calories and or alcohol (diet-induced in hypertriglyceridemia).Very low density lipoprotein secretion that can also increase secondary to diabetes and obesity or other medical problems (secondary hypertriglyceridemia). Primary, hypertriglyceridemia were occurs because of an over production of triglycerides and very low density lipoprotein particles and were often associated with other medical conditions including in diabetes and obesity. Hypertriglyceridemia, was not usually an isolated condition. It tends to be associated with that patients who are having low concentrations of HDL cholesterol and elevated levels of LDL particles, posing the risk for atherogenesis.Mixed hyperlipidemias, are the most common forms of dyslipidemia where patients may have elevations in both triglyceride and cholesterol levels.

Familial combined hyperlipidemia occurs in approximately 1 in 100 were in the population where patients over produce very low density lipoprotein particles because of an increased production of Apo lipoprotein B. This increases the production of very low density lipoprotein particles that can result in an elevated triglyceride level,an elevated cholesterol level (since VLDL particles may be converted to LDL particles that which were not cleared rapidly and from the system and accumulate), or both in an elevated triglyceride and cholesterol level. The features of familial combined hyperlipidemia that may present differently in members of the same family, may even change in a given individual. In general, however an elevated Apo lipoprotein B concentrations, the presence of hypercholesterolemia or hypertriglyceridemia, that can be found in family members with CAD.

There may be a familial basis for the mixed hyperlipidemia, that which may result from a deficiency of the lipoprotein lipase enzyme. This deficiency, were leads to a reduced ability to delipidize, the triglyceride molecules from that VLDL and chylomicron particles. Depending on that situation triglyceride levels can increase moderately or severely placing the patient in that at risk for developing the Pancreatitis. Therefore the goal of therapy for these patients is to reduce triglyceride concentration that can prevent pancreatitis. (Peggy K Han, 2003)

Etiology

The etiology can be classified as, primary and secondary causes.

Primary causes are due to single or multiple gene mutations resulting in a disturbance of glyceride production or clearance. They vary in location of genetic defect, inheritance pattern, prevalence, clinical features, and treatment. All least 18 separate entities have been

described. The suspicion for a primary lipid disorder should be especially high in patients with premature atherosclerotic disease, a family history of early atherosclerotic disease, a significantly elevated serum cholesterol level (>240 mg/dl) and physical signs of hyperlipidemia. Most adult cases of dyslipidemia are secondary in nature. In western civilizations, sedentary lifestyle and excessive consumption of saturated fats, trans-fatty acids and cholesterol are the most important secondary causes. Certain medical conditions are commonly associated with dyslipidemia, including chronic renal insufficiency, renal failure, diabetes mellitus, hypothyroidism, cholestasis liver disease, and alcohol dependency. Certain drugs including high-dose thiazide diuretics, oral estrogens, glucocorticoids, anabolic steroids, and atypical antipsychotics, such as olanzapine and clozapine have also been implicated in causing mid-to-moderate degrees of dyslipidemia. Several disorders, that are passed down through the families that can led to abnormal cholesterol and triglyceride levels. They include:

a) Familial Combined Hyperlipidemia

b) Familial Dysbetalipoproteinemia

c) Familial Hypercholesterolemia

a) <u>Familial combined Hyperlipidemia</u>

Familial combined Hyperlipidemia was a disorder of an high cholesterol and high blood triglycerides that is inherited, which means that it was passed down through families.

Alternative names: Multiple lipoprotein-type hyperlipidemias

Causes: Familial combined Hyperlipidemia was the most common genetic disorder, of that increased blood fats that can causes early heart attacks. However, researchers were not yet identified the specific genes responsible. Diabetes, alcoholism and hypothyroidism, that can make the condition worse. Risk factors, which include a family history of high cholesterol and previous coronary artery disease.

Symptoms: chest pain (angina) may occur.

b) Familial dysbetalipoproteinemia

Familial dysbetalipoprotemia was a disorder passed down through the families in which there were in high amounts of cholesterol and triglycerides in the blood.

Alternative names: Type 3 hyper lipoproteinemia, Deficient or defective Apo lipoprotein

Causes: A genetic defect, that causes this condition. The disease is linked to defects in the gene for Apo lipoprotein E in many cases. Hypothyroidism, Obesity, or diabetes can make the condition worse and risk factors for familial dysbetalipoprotenemia, that include in a family history of the disorder or coronary artery disease.

Symptoms: Symptoms, may not been seen until age 20 or older. Yellow deposits, of fatty material in the skin called xanthomas may appear on the eyelids, palms of the hands, soles of the fee or in the tendons of the knees and elbows. Atherosclerosis is develops at an early age. There may be early chest pain (angina) and or decreased blood flow to specific parts of the body and causing transient ischemic attacks of the brain, peripheral artery disease.

c) Familial hypercholesterolemia:

Familial hypercholesterolemia is a disorder of high LDL ("bad") cholesterol that was passed down through families, which means that it was inherited. The condition of begins at birth an that can cause heart attacks at in an early age.

Alternative names: Type 2 hyperlipoproteniemia, Hypercholesterolemia xanthomatosis, Low density lipoprotein receptor mutation. Causes: familial hypercholesterolemia, was the genetic disorder that was can caused by a defect on chromosome 19.

Symptoms: that may occur include:

- Fatty skin deposits called xanthomas,that in the of over the elbows, knees and buttocks, tendons and around the cornea of the eye.

- Cholesterol deposits in that eyelids (xanthelasmas)
- Chest pain (angina) or were the other signs of coronary artery disease; may be present in an young age.(Pearson T A et al,1999)

Pathophysiology

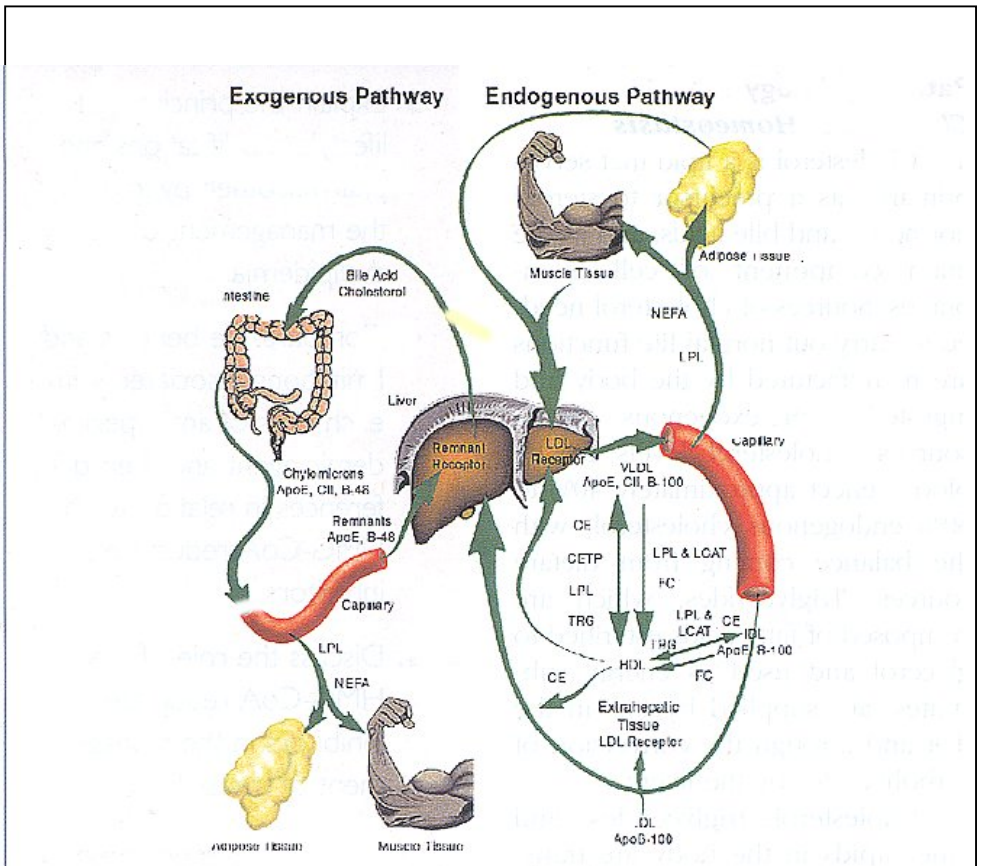
Cholesterol Homeostasis

Cholesterol was a lipid, that can serves primarily as a precursor to steroid hormones, bile acids, as the main component of the cell membranes. Sources of the cholesterol needed to carry out of normal life functions were manufactured by the body and ingested from exogenous dietary sources. Cholesterol levels were the blood, reflect approximately 40% to 60% endogenous cholesterol and with the balance coming, from dietary sources. Triglycerides which are composed of fatty acids esterified to glycerol and used as energy substrates, were supplied by fats in that diet, through the conversion of carbohydrates by the liver.

Cholesterol and triglycerides were other lipids in that body were transported through that bloodstream in a spherical particles, called lipoproteins. Lipoproteins can be divided, into five major categories depending on that composition.

The classes from largest and least dense to smallest and most dense are chylomicrons and (VLDL), (IDL),(LDL), and (HDL). The larger more particles primarily were have a triglyceride-rich core, while the smaller, more dense particles

have a cholesterol ester core. LDL,that can accounts for approximately 60% to 70% of total serum cholesterol and was the primary atherogenic class of lipoproteins. High density lipoprotein constitutes approximately 20% to 30% of total serum cholesterol with vey low densiy lipoprotein comprising about 10% to 15%.Cholesterol was derived from two sources: exogenously from the systemic circulation and endogenously via intracellular synthesis (Figure 1).



Apo = apolipoprotein; CE = cholesteryl ester; CETP = cholesteryl ester transfer protein; FC = free cholesterol; HDL = high-density lipoprotein; IDL = intermediate-density lipoprotein; LCAT = lecithin-cholesterol acyltransferase; LPL = lipoprotein lipase; NEFA = nonesterified fatty acids; TRG = triglycerides; VLDL = very-low-density lipoprotein. Adapted with permission from The American College of Clinical Pharmacy, Kansas City, MO.[7]

The exogenous lipoprotein system was responsible for the synthesis and transportation and catabolism of chylomicron particles remnants. Saturated

monounsaturated, polyunsaturated fats, cholesterol esters digested,absorbed in the proximal small bowel were reformulated and packaged into chylomicrons by cells in the intestinal endothelium. Thus chylomicrons were primarily composed of fatty acids and cholesterol, apolipoproteins that were obtained from the diet. These chylomicrons then that enter the lymphatic system, travel through the body until they were broken down by the enzyme lipoprotein lipase in that capillary beds to chylomicron remnants, which were smaller and contain less fatty acids and but have retained apolipoproteins B-48 and E. These remnants were then cleared from the circulation by the LDL-related receptor protein found in that liver. In addition to replenishing their cholesterol, pools by taking up circulating lipoproteins from exogenous sources and cells that can also synthesize their own cholesterol through the endogenous pathway. The intracellular synthesis of cholesterol involves a series of biochemical reactions starting with acetyl-CoA Figure 2.

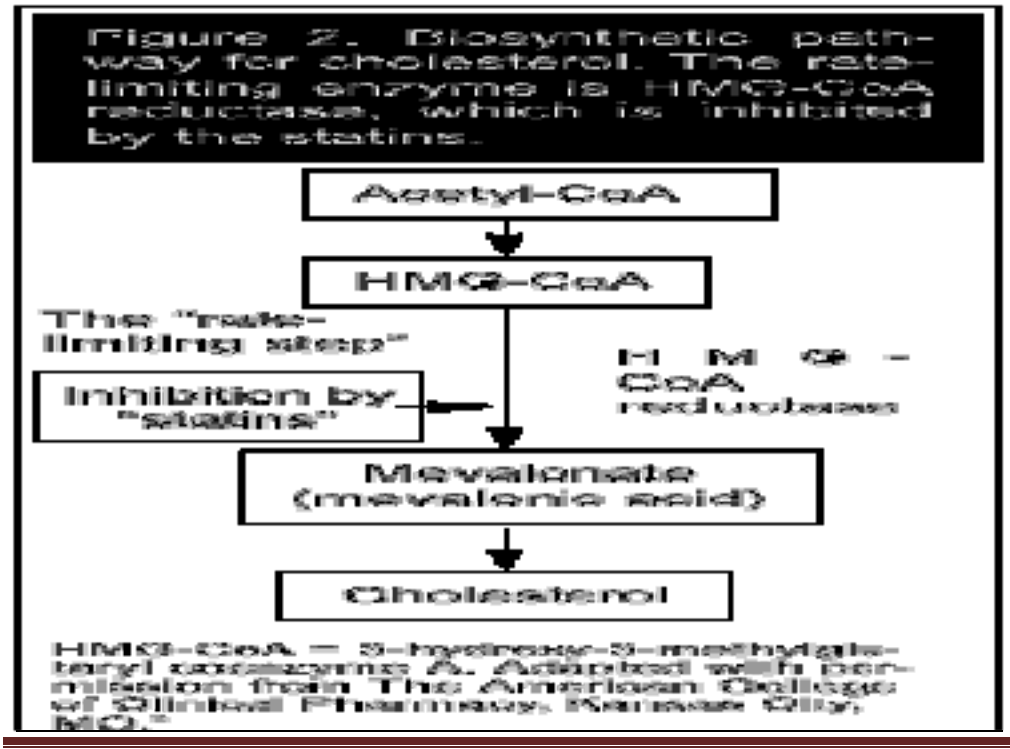


Figure 2. Biosynthetic pathway for cholesterol. The rate-limiting enzyme is HMG-CoA reductase, which is inhibited by the statins.

The rate-limiting enzymes involved in that process were HMG-CoA syntheses and which can catalyzes the conversion of acetyl- CoA to HMG-CoA, and HMG-CoA reductase, in which can catalyzes the conversion of hepatic in HMG-CoA to mevalonic acid, used in a later step in the biosynthesis of cholesterol. The statins, HMG-CoA reductase inhibitors and competitively inhibit this enzyme and reduce the capacity of the cell to synthesize cholesterol.

Fatty acids , cholesterol produced by the body were then transported through the endogenous pathway (Figure 1).Three major lipoproteins,was involved in this pathway. Triglycerides, that can be synthesized by the liver, especially in the presence of excess carbohydrates, later secreted into the bloodstream as VLDL. These very low density lipoprotein particles contain approximately five times more triglycerides than cholesterol and also contain apolipoproteins B-100, E, and C-II. The B,E proteins link with B-E or LDL cell surface receptors while apolipoprotein C-II functions as a cofactor for the enzyme lipoprotein lipase. Once secreted, into the bloodstream and triglyceride molecules were hydrolyzed from the very low density lipoprotein particles by lipoprotein lipase and located in that capillary beds. On release these free fatty acids were used for the energy production primarily by heart and skeletal muscle, or stored in fat cells. Nonetheless, this process of lipolysis decreases the triglyceride content, size of the very low density lipoprotein particles and preparing them for either of their two known metabolic fates.Clearance, via the hepatic remnant receptor and further release of triglyceride resulting in that formation of IDL particles.

IDL particles were high in triglyceride content and contain almost all of the cholesterol initially contained in the VLDL particles. Lipolysis, continues through

the actions of lipoprotein lipase, hepatic lipase and leading to much and smaller cholesterol-rich LDL particles. By this time apolipoproteins, E and C have been removed and leaving only apolipoprotein B-100 on the LDL particles. IDL particles were intermediate products between VLDL and LDL particles ,therefore have a short life span. Their cholesterol, triglyceride contents do not significantly impact cholesterol measurements. Except for rare dyslipidemias, less than 5% of cholesterol circulates in that IDL particles. Half of these IDL particles was to cleared from the circulation by the LDL receptor while the other half was converted to LDL particles.

LDL was the primary atherogenic lipoprotein and the smaller the size of the LDL particle the more it was able to penetrate into sub endothelial tissue, where it contributes to the development of atherosclerosis. Excessive circulating, low density lipoprotein cholesterol will cause cholesterol deposition outside of the cell that causing atherogenic plaque in the formation of the vascular endothelium potentially leading to that coronary artery disease.Two specific types of low density lipoprotein particles have recently been identified to be highly associated with coronary heart disease risk. The first, a lipoprotein particle was a very small LDL particle surrounded by a plasminogen-like protein. The other subclass of small dense LDL particles was referred to as atherogenic lipoprotein phenotype B. This subclass was found in an approximately 30% of the population and was associated with a high risk of CHD.

The third major lipoprotein that involved in the endogenous pathway was high density lipoprotein. Similar to low density lipoprotein particles and HDL particles were rich in cholesterol and very small. However high density lipoprotein particles appear to be involved the ireverse cholesterol transport resulting in an anti

atherogenic effect. Specifically high density lipoprotein may prevent or remove cholesterol deposits within the arterial wall. Other possible explanations, for the beneficial role of high density lipoprotein cholesterol include the following: Prevents low density lipoprotien oxidation by working as an antioxidant; Reduces platelet agreeability by increasing prostacyclin production, Stabilizes serum prostacyclin and promotes fibrinolysis, Competitively inhibits the uptake of low density lipo protein by endothelial cells; Prevents LDL aggregation and uptake by macrophages; Decreases cholesterol and foam cell formation; and Inhibits platelet activation by LDL through the phosphatidylinositol cycle.

An important function of high density lipoprotein was that it can serve as a marker for abnormal metabolism of chylomicrons and very low density lipoproteinparticles and because as triglycerides increase and high desnity lipoproteindecreases. Two key enzymes were involved in the transport of cholesterol from the periphery to the liver, where that can be eliminated by particles. Lecithi lipoprotein-cholesterol acyltransferase was responsible for converting the cholesterol in high density lipoprotein particles into insoluble cholesterol esters causing them to partition core of these lipoproteins. The other enzyme and cholesterol ester transfer protein were involved in the transfer of cholesterol esters from HDL particles to triglyceride-rich particles in exchange for triglyceride molecules. Once invery density lipoprotein and intermideate density lipoprotein particles cholesterol was transported to the liver for elimination (Figure 1).

All three lipoproteins were highly involved in that transport of triglycerides and cholesterol from the liver to the body where they may be used by cells and from

the body, to the liver where they may be eliminated. If the amount of cholesterol was insufficient to meet the requirements of any cell, the cell will up-regulate its synthesis of the LDL receptor. The newly formed, LDL receptor will migrate to an area on the surface of the cell called the coated pits. Once in the coated pits the cell was capable of recognizing circulating lipoproteins that contain either apolipoprotein E or B.Both the very low density lipoprotein and IDL particles contain both B and E proteins therefore may have a higher binding affinity for the LDL receptor than the LDL particles. Once binding occurs the lipoproteins are internalized by the cell taken up by liposomes broken down into elemental substances to be used by the cell. The LDL receptor protein returns to the cell surface where it can be bind with another circulating lipoprotein and repeating the process again.

Link Between Cholesterol and CHD

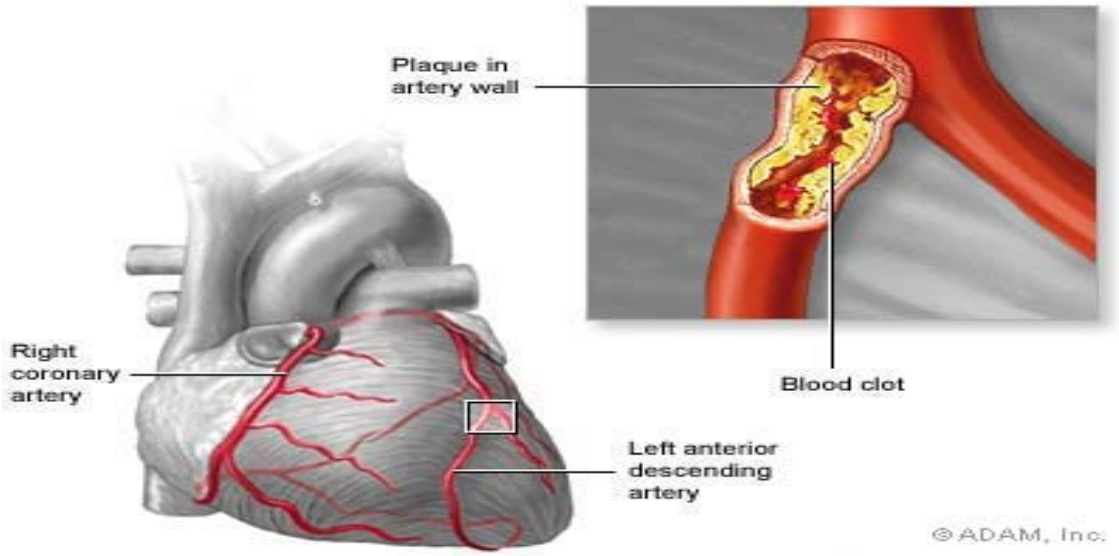
The processes by which lipids and lipoproteins participate in the atherosclerotic plaque formation and CHD events continue to be an area of controversy and research. One of the initiating events of atherosclerotic plaque formation appears, to be the entrance of lipoproteins low density lipoprotein and Lp (a) into the sub endothelial space, with their oxdatively modified free radicals produced by smooth muscle cells and activated macrophage endothelial cells. These oxidatively modified lipoproteins enter macrophages through a scavenger receptor pathway ultimately yielding lipid-rich foam cells. Circulating monocytes were also attracted to smooth muscle, endothelial cells by chemo attractant that was augmented by the oxidatively, modified lipoproteins.

As the macrophage scavenger receptor continues to uptake oxidatively modified lipoproteins foam cells continue to form and progress to the next level of atherogenesis which was in the formation of the fatty streak. At the same time the smooth muscle cells migrate into the sub endothelial space ,begin proliferating contributing to the overall atherogenic process. As the process continue lesions continue to grow by increased smooth muscle cell proliferation was collagen synthesis. At this point and necrosis of the foam cell formation of an extracellular lipid core occurs as long as plasma LDL levels are elevated. The final phase appears to involve in an autoimmune inflammatory response that can causes T lymphocyte infiltration of the adventitia. This inflammatory response that appears to complete the process of plaque formation that wasthe underlying culprit in CHD.

Symptoms

There was no warning signs for high low density lipoprotein and other unhealthy cholesterol levels. When symptoms finally occur they usually take the form of angina (chest pain), heart attack in response to the buildup of atherosclerotic plaque in the heart disease.(Pegg.. k .Han et.al.

2000),



Risk Factors

Unhealthy cholesterol levels increase the risk for heart disease and heart attack. Some risk factors, for cholesterol can be controlled (diet, exercise, weight) while others cannot (age, gender, and family history).

Age and gender:

From puberty on men tend to have lower HDL ("good" cholesterol) levels than women. One reason were that the female sex hormone estrogen was associated with higher HDL levels. Because of this, pre menopause and as estrogen levels and decline women, catch up in their rates of heart disease. Throughout the menopausal years and high density lipoprotein levels decrease and bad cholesterol and triglyceride levels increase. For men, low density lipoprotein and triglyceride levels

also rise as the age and the risks for heart disease increase as well.There was some evidence that high triglyceride levels carry more risks for women than men.Heart disease, was the main cause of death for both men and women.

Children and adolescents:

Children, who have abnormal cholesterol levels were at increased risk of developing that heart disease later in the life. However, it was difficult to distinguish "normal" cholesterol levels occur between genders and population groups. Cholesterol levels tend to naturally rise sharply until puberty and decrease sharply, then that rise again.

Genetic factors and family history:

Genetics play an major role in determining a person blood cholesterol levels.children from families with a history of premature heart disease should be treated for cholesterol levels after they are 2 years old. Genes may influence whether a person have low high density lipoprotein levels, high low density levels, high triglycerides and high levels of other lipoproteins such as lipoprotein(a).

Inherited cholesterol disorders include:

- ✓ Familial hypercholesterolemia was a genetic disorder that causes high cholesterol levels and particularly LDL, premature heart disease. It occurs in an mainly as 1 in 500 people.
- ✓ Familial lipoprotein lipase deficiency was a very rare disorder that causes depletion of lipoprotein lipase. This was an enzyme that appears to be important in the removal of lipoproteins that were rich in triglycerides. People who were deficient in it have high levels of cholesterol , fat in their blood.

Life style factors:

Diet: The primary dietary elements that can lead to unhealthy cholesterol include saturated fats (found mainly in red meat, egg yolks, and high-fat dairy products) and transfatty acids (found in fried foods and some commercial baked food products).shellfish was also high in dietary cholesterol.

Weight: Being overweight, obese increases the risk for unhealthy cholesterol levels.

Exercise: Lack of exercise can contribute to weight gain, decrease lipoprotein in that high density lipoprotein in HDL levels and increase in LDL and total cholesterol levels.

Smoking: Smoking reduces that HDL cholesterol and promotes build-up of fatty deposits in the coronary arteries.

Obesity, Metabolic syndrome, and type 2 diabetes:

The effect of obesity on cholesterol levels is complex. Overweight individuals tend to have high triglycerides ,LDL levels ,low HDL levels. This combination was a risk factor for heart disease. Obesity also causes other effects (high blood pressure, increase in inflammation) that pose major risks to the heart. Obesity was particularly dangerous when it is one of the components of the metabolic syndrome formerly known as syndrome x. This syndrome consists of obesity marked by abdominal fat and unhealthy cholesterol levels and high blood pressure,insulin resistance. Metabolic syndrome wasa pre-diabetic condition that is significantly associated with heart disease and higher mortality rates from all causes. Many doctors recommend that patients with metabolic syndrome should be aggressively treated with high-dose statin therapy to lower LDL levels.

Obesity was also strongly associated with type 2 diabetes, which itself poses a significant risk for high cholesterol levels and heart disease.

Children who are overweight was at higher risk for high-triglycerides and low HDL, which may be directly related to later unhealthy cholesterol levels. Childhood LDL levels and body-mass index (BMI) were strongly associated with cardiovascular risk during adulthood. Overweight and obese children who have high cholesterol should also get tested for high blood pressure and diabetes other conditions associated with metabolic syndrome.(Fredrickson D S et al,1967)

Other Medical Conditions:

- **High blood pressure:**

High blood pressure (hypertension) contributes to the thickening of heart's blood vessel wall which can worsen atherosclerosis (accumulated deposits of cholesterol in the blood vessels).High blood pressure high cholesterol, diabetes all work together to increase the risk for developing heart disease.

- **Hypothyroidism:**

Low thyroid levels (hypothyroidism) were associated with higher risk for high total and low density lipoprotein cholesterol, and triglycerides. Treating the thyroid condition that can significantly reduce cholesterol levels. Research was mixed on

whether mild hypothyroidism (subclinical hypothyroidism) was associated with unhealthy cholesterol levels.

- **Polycystic ovarian syndrome:**

Women with this endocrine disorder may have increased risk for high triglyceride and low HDL levels. This risk, may be due to the higher levels of the male hormones testosterone associated with this disease.

- **Kidney Disease:**

Kidney disease, increases the risk of heart disease.

- **Other risk factors:**

Medications. Certain medications, such as specific antiseizure drugs, corticosteroids,isotretinoin (Accutane) may increase lipid levels.

Diagnosis

Blood tests can easily measure cholesterol levels. A blood test for cholesterol,that should include the entire lipoprotein profile low density lipoprotein, total cholesterol,high density lipoprotein and triglycerides. It is very difficult to measure low density lipoprotein levels by themselves and but low density lipoprotein levels can reliably calculated using total cholesterol and high density lipoprotein levels.

To obtain a reliable cholesterol reading, doctors advise:

- Avoid strenuous exercise for 24 hours before the test.
- Do not eat and drink anything but water for 12 hours forehand.

- If the test results were abnormal in second test should be performed between 1 week and 2 months after the first test.(Lichtenstein A H et al, 2006)

Screening Guideline:

Periodic cholesterol testing was recommended in all adults and but the major national guidelines differ on the age to star testing.

- Recommended starting ages, were between 20-35 for men and 20-45.
- Adults with normal cholesterol, diabetes, kidney problems, heart disease, and other conditions require more frequent testing.

Screening with a fasting lipid profile recommended for children WHO:

- Have risk factors such as family history of high cholesterol and history of heart attacks before age 55 for men and before age 65 for women. Screening should begin as early as age 2 and no later than age 10.
- Are Obes or who have diabetes. If the child's cholesterol level tests normal and retesting was recommended in 3-5 years. Patients already being treated for high cholesterol should every 2-6 months. (Stefanick M L et al, 1998)

Treatment Approach

Lowering cholesterol level reduces risk of heart disease and stroke. Studies that have shown that for every 1% reduction in cholesterol levels there was a 25% reduction in the rate of heart disease. People who already have heart disease or are at higher risk, benefit most from lowering their cholesterol.

Life style:

A number of lifestyle changes were recommended in those with high cholesterol including: smoking cessation and limiting alcohol consumption,

physical activity and maintaining a healthy weight and a diet low in saturated fats. In strictly controlled surroundings, a diet that can reduce cholesterol levels by 15%.In practice dietary advice can provide a modest decrease in cholesterol levels and may be sufficient, in the treatment of mildly elevated cholesterol.(Tosi I et al, 2007)

Medications:

If low density lipoprotein cholesterol remains high after changing diet and exercise habits doctor may prescribe medications to lower it. If cholesterol,was very high (more than 200mg/dl) may start drug therapy, at the same time improve our diet and exercise habits. Drugs commonly used to treat high cholesterol include. (Jones P H,et al,2003)

a. Statins

Statins were the most effective drugs for the treatment of high cholesterol, particularly for lowering LDL levels. They also have modest effects in lowering triglycerides, increasing HDL levels. Statins inhibit the liver enzyme HMG-COA reductase, which the body uses to manufacture of cholesterol. These drugs effectively, reduce the risk of major coronary events including first and second heart attacks and stroke in adults with unhealthy cholesterol levels.

Brands: statins, approved in the U.S include:

- Lovastatin,Pravastatin,Simvastatin, Fluvastatin,Atorvastatin,Rosuvastatin

Statins, may also be prescribed fixed dose combination drugs which combined two drugs in one pill: Statins that may be prescribed along with other cholesterol-lowering drugs such as bile acid binding resins and nicotinic acid and fibrates.

b) Niacin (Nicotinic acid):

Brands: Nicotinic acid was the active compound found in niacin, or vitamin B3.It was a particularly helpful choice for patients with low high density lipoprotein levels. Brands include Niacor, Nicolar and slo-Niacin. An extended release forms (Niaspan), administered at bedtime, may have fewer side effects, including headaches and flushing, than rapidly-acting Niacin drugs. Although niacin was available over the counter and the active form used for cholesterol treatment was given in much higher doses. It was an important to take this medication under a doctor's direction in order to ensure its safety and effectiveness. (Weis M R et al, 2000)

Benefits: When used in high doses niacin has the following benefits:

- Rasies HDL levels higher than other anti-cholesterol drugs.
- Reduces, triglyceride levels are very effectively.
- Lowers low density lipoprotein-cholesterol and lipoprotein (a)
- Costs, less than other anti-cholesterol drugs.

C) Fibrates:

Brands: Fibrates that,break down the particles that make triglycerides. Gemfibrozil was standard fibrate. It was usually taken twice a day and 30 minutes before breakfast, before the evening meal. Other fibrates includes fenofibrate and benzafibrate .This may be in more effective lowering cholesterol than gemfibrozil. (Baigent C et al, 2007)

Benefits: Fibrates were having the following effects on cholesterol and lipids other factors:

- They were good choices for many patients who need to lower triglyceride levels, increase HDL but who cannot take other drugs used for these purpose, such as nicotinic acid.
- Fibrates that can produce modest reductions in LDL levels, although not as effectively as statin or other drugs. LDL may actually increase in patients with very high triglycerides who take these drugs. (The newer fibrates are much more effective in lowering LDL than gemfibrozil).
- Fibrates, that may lower the risk of heart attack.

D) Bile-Acid Binding Resins

Bile-acid binding resins work and as their name suggests by binding to bile in the digestive tract. This reduces cholesterol in that following way,

- Bile was made in the liver and was used as one of the body's primary manufacturing components.
- Once the resins bind to bile in the digestive tract the bile in the digestive tract andthe bile is excreted in feces.
- As the resins eliminate bile from the body and the liver takes more cholesterol from the blood stream in order to produce more bile.
- As cholesterol was taken out of the blood stream LDL levels drop.

E) Ezetimibe:

Ezetimibe blocks absorption of cholesterol that comes from food.Ezetimibe was usually prescribed alone as in combination with fenofibrate for reduction of total cholesterol and low density lipoprotein in patients with mixed hyperglycemia (high LDL levels, high triglycerides, Low HDL levels) whose cholesterol has not been adequatly, controlled through diet alone.(Byington R P et al,1995)

Guidelines:

Various clinical practice guidelines have to addressed the treatment of hypercholestrolemia.The American College Of Physicans, have be addressed that the treatment of hypercholesterolemia in patients with diabetes. Their four recommendations are:

1. Lipid-lowering therapy should be used for secodary prevention of cardiovascular mortality, morbidity for all patients "(both men and women) with known coronary artery disease ,type 2 diabetes.

2. Statins should be used for primary prevention against macrovascular complications in patients (both men and women) with type 2 diabetes and other cardiovascular risk factors.

3.Once lipid-lowering therapy is initiated, patients with type 2 diabetes mellitus should be taking at least moderate doses of statin (the accompanying evidence report states “simvastatin,40 mg/dl;pravastatin,40 mg/dl;atorvastatin,20 mg/d; or an equivalent dose of another statin”).

4. For those patients with type 2 diabetes who are taking statins,routine monitoring of liver function tests or muscle enzymes is not reccommended except in specific cirumstances.(Kawada T et al, 2002)

Alternative Medicine

According to survey in 2002,alternative medicine was used in an attempt to treat cholesterol by 1.1% of U.S adults.Consistent with previous surveys,this one found that the majority of individvals (i.e.,55%) used it in conjuction with conventional medicine.A review trials of phytosterols and/or phytostanols reported an average of 9% lowering of LDL –Cholesterol.In 2000 the food and Drug Administration approved the labelling of foods containing specified amounts of phytosterol esters or phytostanols esters as cholesterol lowering;in 2003 an FDA Interim Health Claim Rule extended that label claim to foods or dietary supplements delivering more than 0.8 grams/day of phytosterols or phytostanols.Some researchers,however,are concerned about diet supplementation with plant sterolesters and drawn attention to significant safety issues.(Brugts J J et al,2009)

Health Related Quality Of Life

Definition:

Health related quality of life is a multi-dimensional concept that can encompasses the physical and emotional andsocial components that associated with

an illness or its treatment. There are five main dimensions of HRQoL: (1) physical functioning, (2) psychological functioning, (3) social functioning, (4) cognitive functioning, and (5) general well-being (John E. Warw, Jr., PhD et.al., 2008).

Sf-36v2 Health Survey

The sf-36v2 Health survey (SF-36V2; ware et al;2007) is developed to be a brief, board, generic measure of eight domains, or aspects of health status that are considered important in describing and monitoring individuals suffering from a disease/illness. Although it measures these domains in the terms of functioning, behaviorally more subjective states and or personal evaluations, it is not intended to be a comprehensive survey of health. The SF-36V2 maintains comparability with its predecessor, the SF-36 Health Survey (SF-36) by retaining and improving on the same domains, component summary measures, and items the original version of the instrument.

This SF-36V2 administration guide was developed to meet the needs of clinical trial investigator using electronic SF-36V2 scoring and reporting services from quality metric incorporated. The focus of this guide is to provide investigators administering the SF-36V2 as part of a clinical trial with the information required to administer the instrument and to then correctly enter valid data obtained from the administration. To assist in this task, a description of SF-36V2 concepts, measures and forms is first provided as an introduction to administration, data entry, and data quality guidelines. (Ware et al.,2007)

Health Domain Scales.

The SF-36V2 includes one favorably scored scale measuring each of eight health domains: Physical health problems (role-physical), bodily pain, General

health, Vitality, Social Functioning, Role participation with emotional health (role-emotional) and mental health. (Kosinski, Ware,Bayliss et.al.,1995)

Physical Functioning (PF)

The content of the 10 item PF scale reflects the importance of distinct aspects of physical functioning and necessity of sampling a range of severe and minor physical limitations. Items represent levels and kinds of limitations between the extremes of physical activities, including lifting and carrying groceries; climbing stairs; bending, kneeling, or stopping; and walking moderate distance. One self-care item is included to represent limitations in self-care activities. The Physical functioning items capture both the presence and extent of physical limitations in self-care item is included to represent limitations in self-care activities.(Garratt,A,N.,Schmidit,L.,Mackintosh et.al.,(2002)

Role-Physical (R.P)

The four-item role-physical scale covers an array of physical health-related role limitations, including (a) Limitations in the kind of work or other work or other usual activities, (b) reductions in the amount of time spent on work or other usual activities, (c) difficulty performing work or other usual activities, (d) accomplishing less.

Bodily Pain (BP)

The BP scale comprises two items: one pertaining to the intensity of bodily pain and one measuring the extent of interference with normal work activities due to pain. Low scores indicate high levels of pain that impact normal activities, whereas high scores indicate no pain and no related impact on normal activities.

General Health (GH)

The GH scale consists of five items, including a rating of health (excellent to poor) and four items addressing the respondent's views and expectations of his or her health. Low scores indicate evaluation of general health as poor and likely to get worse. High scores indicate that the respondent evaluates his or her health most favorably.

Vitality (VT)

This four-item measure of vitality (i.e., energy level and fatigue) was developed to capture differences in subjective well-being. Low sores indicate feelings of tiredness and being worn out. High scores indicate feeling full of energy all or most of the time.

Social Functioning (SF)

This two-item scale assesses health-related effects on quantity and quality of social activities, asking specifically about the impact of either physical or emotional problems on social activities.

Role-Emotional (RE)

The three-item RE scale assesses mental health-related role limitations in terms of (a) time spent doing work or other usual activities, (b) amount of work or activities accomplished, and (c) the care with which work or other activities were performed.

Mental Health (MH)

The five-item MH scale includes one or more items from each of four major mental health dimensions (anxiety, depression, loss of behavioral/emotional control, and psychological well-being).Low scores on MH are indicative of frequent feelings

of nervousness and depression, whereas high scores indicate feelings of peace, happiness, and calm all or most of the time.

Reported Health Transition (HT)

A general health item asks respondents to rate the amount of change they experienced in their health in general over a 1-year period on the standard (4-week) form or over a 1-week period on the acute (1- week) form.

Physical And Mental Component Summery (Pcs And Mcs Measures)

The measurement model, or conceptual framework, underlying the construction of the SF-36V2 multi-item health domain scales and component summery measures. This model has three levels:

(a) Items, (b) health domain scales that aggregate items, (c) component summary measures that aggregate the health domain scales.

The aggregates of the health domain scales are referred to as component summary measures because they were derived and scored using a factor analytic method called principal components analysis (Harman, 1976).Although they reflect the two broad components or aspects of health-physical and mental-all of the eight health domain scales are used to scores both component summary measures. All but one of the 36 items (item2, self-reported health transition). (Ware,J.E.,Jr.,Snow,K,K.,(1993).

Table 1: Abbreviated Item Content For Health Domain Scales

ITEMS	SCALES	Dimensions
3. Vigorous activities	Scale 1: Physical Functioning (PF)	Dimension A: PHYSICAL HEALTH
4. Moderate activities		
5. Lift, carry groceries		
6. Climb several flights		
7. Climb one flight		
8. Bend, kneel		
9. Walk mile		
10. Walk several blocks		
11. Walk one block		
12. Bathe, dress		
13. Cut down time	Scale 2: Role-Physical (RP)	
14. Accomplished less		
15. Limited in kind		
16. Had difficulty		
21. Pain-magnitude	Scale 3: Bodily Pain (BP)	
22. Pain-interfere		
1. General health rating	Scale 4: General Health (GH)	
36. Excellent		
34. As healthy as anyone		
33. Sick easier		
35. Health worse		
23. Pep/life	Scale 5: Vitality (VT)	
27. Energy		
29. Worn out		
31. Tired		
32 Social-extent	Scale 6: Social Functioning (SF)	
20. Social-time		
17. Cut down time	Scale 7: Role-Emotional (RE)	
18. Accomplished less		
19. Not careful		
24. Nervous	Scale 8: Mental Health (MH)	Dimension B: MENTAL HEALTH
25. Down in dumps		
26. Peaceful		
28. Blue/sad		
30. Happy		
2. Change in reported health		

LITERATURE REVIEW

1.J.Muller-Nordhorn,et.al.,(2011),was conducted a study of effect of an adherence-enhancing program on HRQoL of life in patients with hypercholestrolemia.In study Health-related quality of life (HRQOL) is an important outcome.HRQOL has been shown to be associated with adherence to medication and lifestyle recommendations.Result of this study is a total of 7640 patients are included.HRQOL was inversely related to disease severity in all scales but the mental SF-12 summary scale.Patients in the adherence program had significantly higher physical SF-12 scores during follow-up compared to controls,independent from any lipid-lowering effect.The conclusion of this study is the adherence-enhancing program had a significant benefit on physical HRQOL in patients with statin therapy.However,the benefit was not associated with improved adherence to lipid-lowering therapy on the individual level and thus should rather be understood a unspecific program effect.Also, the obsereved effect does not appear to be clinically relevant

2.Nelva Mata,Rodrigo Alonso et.al.,(2011),reported a cross-sectional study of clinical characteristics and evaluation of LDL-Cholesterol treatment of Spanish Familial Hypercholestrolemia Longitudinal Cohort study.Method and Result of this study is demographic,lifestyle,medical and therapeutic data were collected by specific surveys.Data from 1852 subjects (47.5% males) over 19 years old were analyzed: 1262 (68.1%,mean age 45.6 years) had genetic diagnosis of FH and 590 (31.9%.mean age 41.3 year were non-FH.Conclusion of the study is most of this high risk population is receiving LLT,prevalence of cardiovascular disease and LDL-c levels are still high and far from the optimum LDL-c therapeutic

goal.However,LDL-c levels could be reduced by using more intensive LLT such as combined therapy with maximum statin dose and ezetimibe.

3.Vilma Raskeliene,Marijia Ruta Babarskine,et.al.,(2009),conducted a study of Impact of duration and treatment of arterial hypertension on health-related quality of life.The method a total of 101 patients (19 males and 82 females) met the inclusion criteria and consented to participate in the study,Their mean age was 58.03+_5.63 years.The patients quality of life was evaluated using the medical outcomes study short form 36- item questionnare (SF-36 questionnare),which comprises 36 questions grouped into eight domains.The result of the study is subjects with AH showed lower values compared to normotensive patients in the following domains:Physical functioning (p=0.014),role limitations due to physical health (p=0.012),energy/vitality (p=0.016),and general health evaluation (p=0.023).This study concluded that the patients with AH reported lower quality of life in the following domains:physical functioning,role limitations due to physical health,energy/vitality,and general evaluation of health.Compared to patients without AH,the quality of life of the patients who had the effective treatment did not differ,whereas patinets with ineffective treatment had the lower quality of life.Functioning is more statistically significantly limited due to physical health in patients with AH.

4.Ford ET .AL., (2008) conducted a cross-sectional study of gender difference in coronary heart disease and health related quality of life:finding from 10 states from the 2004 behavioral risk factor surveillance system.The main objective of this study was to examine differences in health-related quality of life (HRQoL) between people with coronary heart disease (CHD) and those without this condition in

population based sample of U.S. adults and toexamine the interaction between CHD and diabetes on HRQoL.The result of study was performed a cross sectional analysis of data from 50,573 participants aged >_ 18 years from 10 states of the 2004 Behavioral Risk Factor Surveillance system(BRFSS).Data were self-reported.They concluded that the people with CHD have significantly improved HRQoL Compared with those without CHD.HRQoL among women with CHD is worse than that among men with CHD.

5. Didem Arslantas,Unal Ayranci,et.al.,(2008)was conducted a population based cross-sectional study of prevalence of hypertension among individuals aged 50 years and over and its impact on health related quality of life in a semi-rural area of western Turkey.The method of this study is population based cross-sectional study was conducted in two settlements ina region of western Turkey between March 1 and April 30.2007. A questionnaire concerning life habits associated with hypertension,medical histories,and demographic characteristics is filled in by a face to face interview.The SF-36 scale is used to assess HRQoL.Body mass index (BMI) is calculated by measuring the weight and length of the body.The result of this study is HRQoL is better in hypertensive patients whose blood pressure is under control, whereas it isworse in those with at least one chronic disorder accompanying hypertension (p<_0.05,for each one).This study concluded that great emphasis should be placed on the need for a public health program for the detectio,prevension, and control of hypertension, including other risk factors,as well as for the modification of foods and life habits,specifically in individuals who are most likely to be at risk of hypertension.

6.Ashraf Eljedi,et.al.,(2006) was conducted a Health related quality of life in diabetic patients and controls without diabetes in refugee camps inGaza strip:a cross-sectional study.In this study the prevalence of diabetes mellitus is increasing in developed and developing countriesDiabetes is known to strongly affect the health-related quality of life (HRQoL).HRQoL is also influenced by living conditions.The result of the study that all domains were strongly reduced in diabetic patients as compared to controls,with stronger effects in physical health (36.7 vs 75.9 points of the 0-100 scores) and psychological domains (34.8 vs 70.00 and weaker effectsin social relationships (52.4 vs 71.4) and environment domains (23.4 vs 36.2).The impact of diabetes on HRQoL was especially severe among females and older subjects (above 50 years).Low scioecnomic status had strong negative impact on HRQOL in the younger age group (<50 years).The conclusion of the HRQoL is strongly reduced in diabetetic patients living in refugee camps in the Gaza strip.Women and older patients are especially affected.

7.**I-C Huang,et.al.,(2006)** reported a study based on the relationship of excess body weight and health-related quality of life:evidence from a population study in Taiwan.The method of the cross-sectional study used a national representive sample (n= 14221) from the 2001 Taiwan National Health Interview survey.Body weight was categorized using body mass index (BMI in kg/m2) as normal (18.5-24.9), overweight (25-29.9), and obese (>- 30).HRQoL was measured using the Taiwan version of the SF-36. The result of the study is unadjusted physical HRQoL was best for normal weight,worse for overweight, and worst for obese individuals.For unadjusted mental HRQoL, overweight subjects had at least as good mental domain scores of HRQoL as those with normal weight or obesity,depending on the

subscales.This study is concluded that in Taiwan,excess weight was related to worse physical,but not mental HRQoL.The lack of impact of increased body weight on mental health status presents a potential challenge to preventing the increases in obesity.More Research is needed to elucidate the mechanisms by which excess weight affects specific domains of HRQoL, and to develop effective prevention strategies.

8.Hwee-Lin Wee,Yin-Bun Cheung,et.al.,(2005) reported a cross-sectional study in the impact of diabetes mellitus and other chronic medical conditions on health-related quality of life.The main background of diabetes mellitus is an important public health concern,the impact of which is increased by the high prevalence of co-exesting chronic medical conditions among subjects with DM.The results of this study is among 5,224 subjects, the prevalence of DM,HTN,HD and MS were 5.9%,10.7%,2.4% and 26.6% respectively.DM lowered SF-36 scores by more than 2 points on 3 SF-36 scales and lowered SF-6D scoresnby 0.03 points.Subjects with DM and HTN,DM and HD or DM and MS experienced further lowering SF-36 scores exceeding 2 points on atleast 6 scales and fruther lowering of SF-6D scores by 0.05,0,08 and 0.10 points respectively.Generally,DM and co-existing medical conditions exerted additive effects on HRQoL,with the exception of DM and heart disease,where a subtractive effect was noted.SF-6D index scores generally reflected the patterns of influence of DM and chronic medical conditions on SF-36 scores.This study concluded that DM and chronic medical conditions generally reduced HRQoL in this multiethnic general population in an additive,rather than synergistic or subtractive fashion.In this study, the SF-6D was a reasonably good summary measure for the SF-36.

9. Hollman.G,Gullberg.M.,et.al.,(2002), reported a descriptive cross-sectional study,to quality of life in patients with familial hypercholestrolemia.In this study,result is patients with FH were significantly more satistfied with overall quality of life 21.8+_ 0-3 (SEM) vs controls 21.1+_ 0.1 and this was also the case in three of four subscales, all differences P<0.05.Anxiety about getting CHD was expressed amongest 86% of the patients with FH.This study concludedthat quality of life amongst patients FH was at least a good as in controls but they were worried about getting CHD.

10.Laura Hyttinen,Paivi kekalainen,et.al.,(2001) was conducted a Health-related quality of life in elderly patients with familial Hypercholestrolemia.In this study concluded that lifelong hypercholesterolemia was not associated with poorer HRQL in elderly survivors of FH.These elderly FH individuals are characterized by their healthy lifestyle and long-term statin treatment.

11.Lyne Lalonde,Ann E.Clarke et.al.,(2001),reported a study based on Health-Related Quality of life with coronary heart disease prevension and treatment.This study estimating the net benefits of dyslipidemia treatment is limited by the lack of comprehensive and standardized information on the preference for dyslipidemia and coronary heart disease.This is a hospital-based study,in this study they measured the health-related quality of life (HRQoL) of healthy participants without dyslipidemia (n= 251) and patients with coronary heart disease (n= 320).compare to the healthy participants without dyslipidemia,those with dyslipidemia reported lower adjusted mean scores on the Rating scale (-2.8 points,p= 0.02) and the SF-36 General Health Scale (-3.3 points,p=0.02).In summary,this study suggests that in primary

prevension, the diagnosis and treatment of duslipidemia may be associated with a small but real reduction in HRQoL.

12.Abdul Rahman Al-Nuaim et.al.,(1996),was conducted a population-based cross-sectional study of population-based epidemiological study on characteristics of risk factors of hypercholerolemia in Saudi Arabia.The result of the study is the risk of developing HC increased with age by 2% and 1 for each year increase in age for borderline high HC and high HC.The risk of developing HC was significantly higher among female subjects.There was no significant regional variation for risk of borderline high HC,however,there was a significant increase in the risk of developing high HC among residents of central and Eastern regions,compared with other regions.The conclusion of this characteristics of risk factors for HC among the Saudi population differ in many respects from other populations.Overweight and obesity are not significant risk factors for HC. Rural communities are more at risk of HC than urban communities.The population of the eastern and central regions were at significantly higher risk of developing HC.The relatively recent urbanization may account for the low prevalence of HC .

AIM AND OBJECTIVE

Aim :

This study aimed to determine the HQRoL study in patients with hypercholestrolemia.

Objective:

1. To assess the health related quality of life in patients with Hypercholesterolemia.
2. To determine the socio-demographic and clinical factors that affects the quality of life of these patients.

PLAN OF THE WORK

- **Preparation of Questionnaire:**

Based on the topic literature review were collected. From the literature review prepare the Performa and SF-36 questionnaire form with the help of standard references. Preparation questionnaire was interviewed by guide and co-guide.

- **Selection of population:**

Sample size calculation was done to determine the population required for the study.To reached the required sample size,200 respondents were selected. From the 200 ,150 patients interviewed. Out of 200, filled questionnaire 150 completely filled questionnaire were selected for the data collection of our study.

- **Data Analysis**

Collected data will be entered in Microsoft excel for analyzing the data. Data processing, tabulation of descriptive statistics, calculation of inferential statistics and graphical representations will be performed primarily using statistical software SPSS for Windows.

METHODOLOGY

This chapter comprised of study site,study period,study population,study design,data collection and data analysis.

1.Study Site

This study conducted in in-patients and out-patients department in Muthoot Medical Centre.It is a teritary care hospital in Pathanamthitta,Kerala,with 750 bedded multispeciality hospitals having Clinical Department such as Medicine,Surgery,Endocrinology,Dermatology,ENT,Urology,Paediatrics,Psychiatry ,Orthopaedic and Gynacology.

2.Study Period

Present cross-sectional study was carried out for a period of 10 months from June 2011 to March 2012

3.Study Population

Study carries out for a period of 10 months from June 2011-2012.

4.Study Design

A cross-sectional study design was conducted to describe the HRQoL in hypercholestrolemia and the scale of SF-36 used to determine the HRQoL of the subjects.

Inclusion Critria

- Familial Hypercholesterolemia
- Age limit above 30
- Hypertension with Hypercholesterolemia
- Hypercholesterolemia with diabetes

- Over weight and obese
- Cigertte Smoking
- Cardio vascular disease
- Stroke

Exclusion Criteria

- ICU patients
- Age limit below 30

5.Data Collection Tool

The study will be a cross-sectional study of patients with hypercholestrolemia attending the Muthoot Medical Hospital,Pathanamthitta Dist,Kerala.

6. Questionnare Form

Questionnare is prepared based on the socio-demographic characteristics of hypercholestrolemia for data collection.The patients of are requested to answer a questionnare.Questionnare includes the demographical data of patients such as age,sex,educational level,martial status,Job,Height,Weight,Familial hypercholestrolemia,use of hypercholestrolemic agents,cholesterol levels in clinical history,other data on laboratory such as blood pressure and fasting sugar levels,life style (smoking cigratte,alcohol) Physical activity,habits(vegetarian and non-vegetarian).

The second part of the questionnare that is SF-36 V2 (study 36 item short form version-2).This SF-36V2 quetionnare form are trademarks of medical outcomes trust and are used under licence (licence no:QM010147).The SF-36 V2 is a National Health Measuremet study.The SF-36 V2 health survey was developed to be a

brief,broad,generic measure of eight domins,or aspects of health status that are considered important in describing and monitoring individuals suffering from a disease or illness.Although it measures these domins in terms of functioning,behaviorally more subjective states and/or personal evaluations.

The SF-36V2 includes one favorably scored scale measuring each of eight health domains.Physical functioning,Role Participation with physical health problems (role-physical),bodily pain,general health,vitality,Social functioning,role participation with emotional health problems (role-emotional),Mental health.

The first and second part of the study was a prospective analysis of files to document the HRQoL in hypercholestrolemia patients.All of the questionnares in the study was those who affected hypercholestrolemia and its risk factors within the last 10 months period prior to the interview.In this study we are enrolled 100 patients according to inclusion criteria.All information was obtained through face-to-face interview.Questions were repeated and seek the information from the patients during the subsequent monts.Time to complete the questionnare was usually between 15-20 minutes.The data regarding the study are made into a report and submitted.

7.Data Processing And Analysis

Collected data will be entered in Microsoft excel for analyzing the data processing,tabulation of descriptive statics,calculation of inferential statistics and graphical representaion will be performed primarily using statical software SPSS for windows.Statistical testing will be performed at 5% level of significance.Baseline characteristics will be described for all patients enrolled in the study.Descriptive

statistics will be provided for all demographic and clinical data.Appropriate statistical test will be used to find out the statistical sibnificance between variables.

7. Ethical Considerations:

Written consent had been obtained from patients attending in the hospital. The respondent had the right to refuse or decide to stop the interview. Patients singed as their agreement to participate in consent form. All of the information will be kept confidentially. College ethical committee approved also has taken.

RESULTS

6. General Description

The present study was carried out in in-patient and out-patient department of Muthoot medical centre, Pathanamthitta dist, Kerala. We are enrolled 100 patients according to the inclusion criteria. Patients were classified according to socio-demographic (age, gender and income), life style (alcoholic and smoker, body weight, exercise, sleep status) habits (vegetarian and non-vegetarian).All these patients were under therapy. The description of the total population is represented in below table 1.

Socio-Demographic Characteristic Disributation

Table 1: Sex Distribution

Sex Distribution	Number of patients
Male	52(53.1%)
Female	46(46.9%)

Age (age greater or less than 40),level of education and the presence of other metabolic risk factors including diabetes, hypertension and BMI classification were controlled for in all models.Rhonda Belue et.al.,2009).

In our study, more number of male patients compare to female.

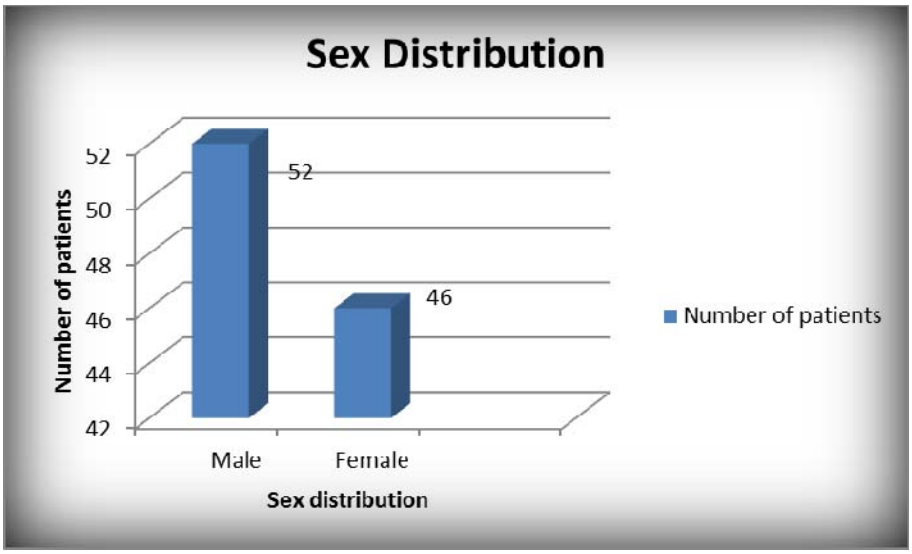


Figure.1: Sex Distribution in hypercholesterolemia

Table 2: Age Distribution

Age group	Number of patients
30-49	8
50-59	15
60-69	36
70-79	27
80-89	12

Healthy lifestyle has been associated with lower risk of incident coronary events among middle-aged women13 and lower risk of CHD mortality in a population of elderly men and women.14 Little is known about the relation between combined healthy lifestyle choices and incident CHD among middle-aged and older men, especially those who are reducing their risk by using drugs for hypertension or hypercholesterolemia. (Stephanie E. Chiuve.et.al.,2006)

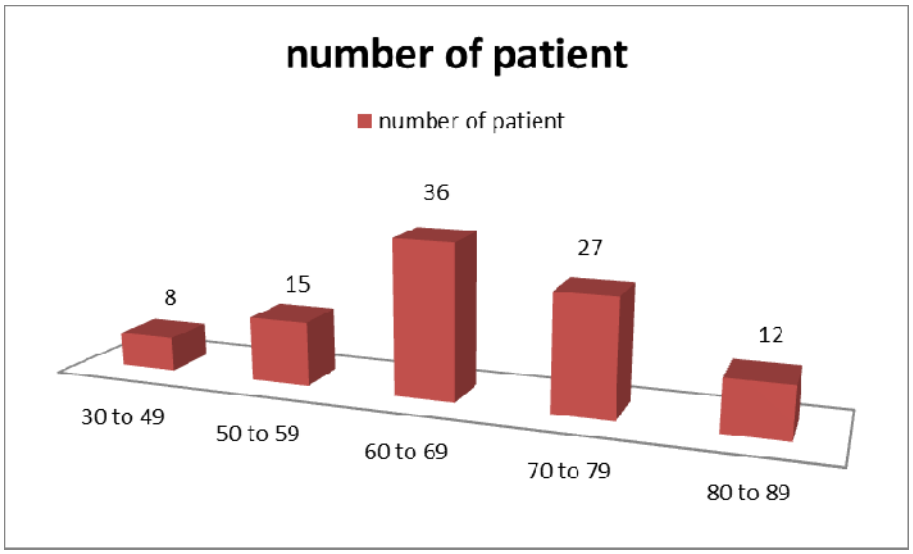


Figure 2: Age distribution in hypercholesterolemia

Among our study, age wise distribution categories into 5 groups. In this group more number of patients between 60-69 age group. Less number of patients in the age group 30-49.In moderate number of patients in 70-79 age group.50-59 category numbers of patients is 15 and 80-89 category number of patients is 12.

Table 3: Education

EDUCATION	NUMBER OF PATIENTS
Primary School	8
Secondary School	53
Higher Study	36

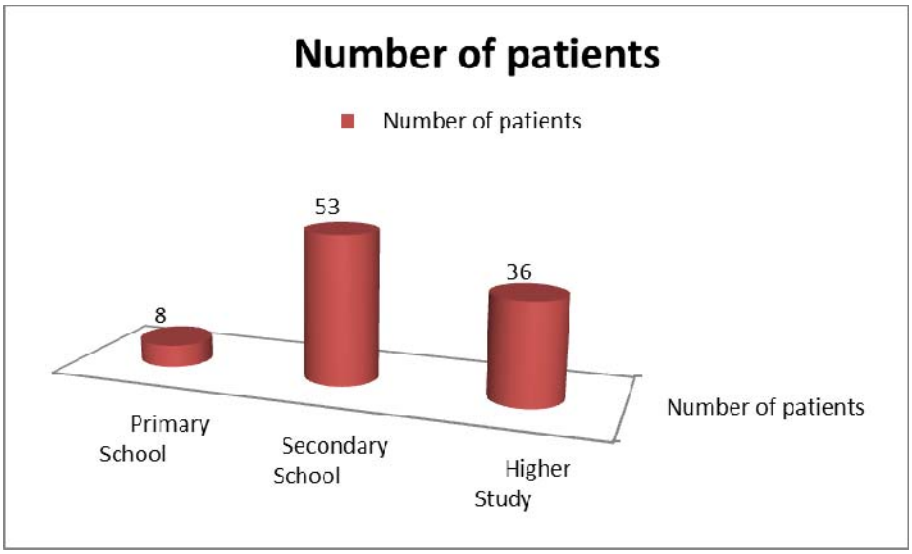


Figure 3: Education Status in hypercholesterolemia patients.

In socio-demographic data's, more number of patients are secondary school level and less number of patients are in primary school. Moderate level of patients is in higher study.

Table 4: Body Mass Index

Body Mass Index	Number of patients
Underweight(18-20)	23
Normal(21-24)	38
Obesity(25-27)	37

BMI ≥ 25 kg/m2 and any two of the following three risk factors:hypertension,hyperlipidemia and diabetes.patrick W.sullivan et.al.,2007. Participants were asked whether a doctor had advised them to eat fewer high fat or high cholesterol foods or to exercise more and also whether they engaged in either action.(Kurt J. Greenlund, PhD.et.al.,1999).

In our present study, more number of patients are in normal category. Just below the normal category number of patients are obese. Body Mass Index in between normal and obesity have only a little range variation. Very less number of patients are underweight category.

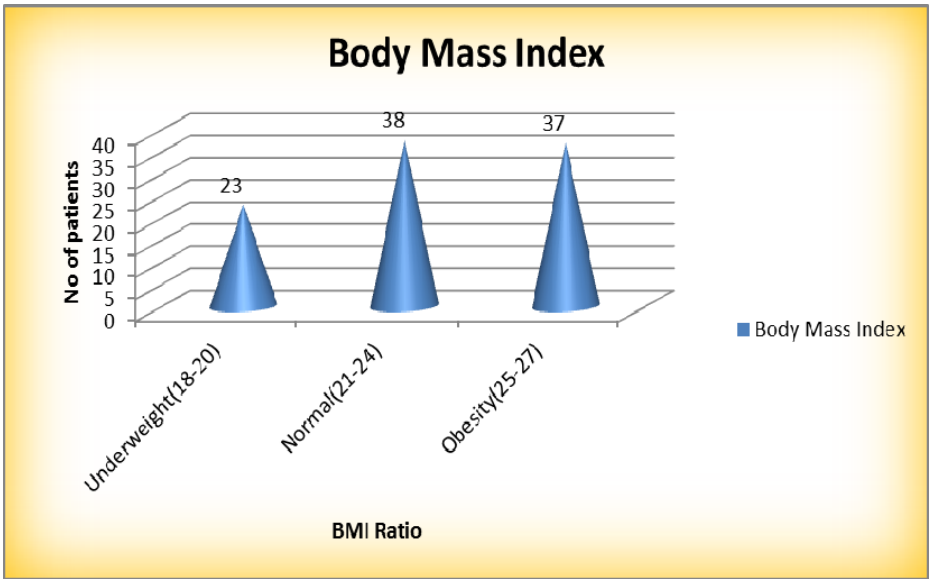


Figure.4: Body mass index in hypercholesterolemia patients

Table 5: Alcoholic Consumption

Alcoholic Consumption	Number of patients
Alcoholic	14(14.3%)
Non-alcoholic	84(85.7%)

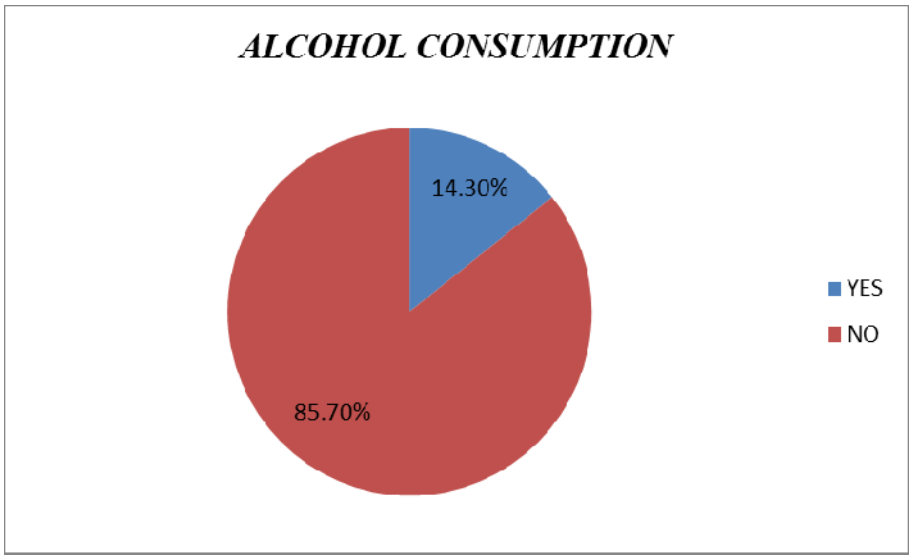


Figure.5: Alcohol Consumption in hypercholestrolemia patient.

In our study alcohol intake patients are less than non-alcoholic. Alcoholic intake patients 14(14.3%) and non-alcoholic patients 84(85.7%).The average daily alcohol intake of 5 to 30 g as low risk. This is consistent with guidelines for moderate alcohol consumption,26 although higher amounts of alcohol intake are associated with lower risk of CHD. (Stephanie E. Chiuve.et.al.,2006)

Table 6: Smoking

Smoking	Number of patients
smoker	59(60.2%)
Non-smoker	39(39.8%)

In socio-demographic data's non-smoker patient is more than smoking patients. The risk of CHD among former smokers declins after smoking cessation, approximating the risk of those who have never smoked after 10 to 14 years. (Stephanie E. Chiuve,et.al.,2006).

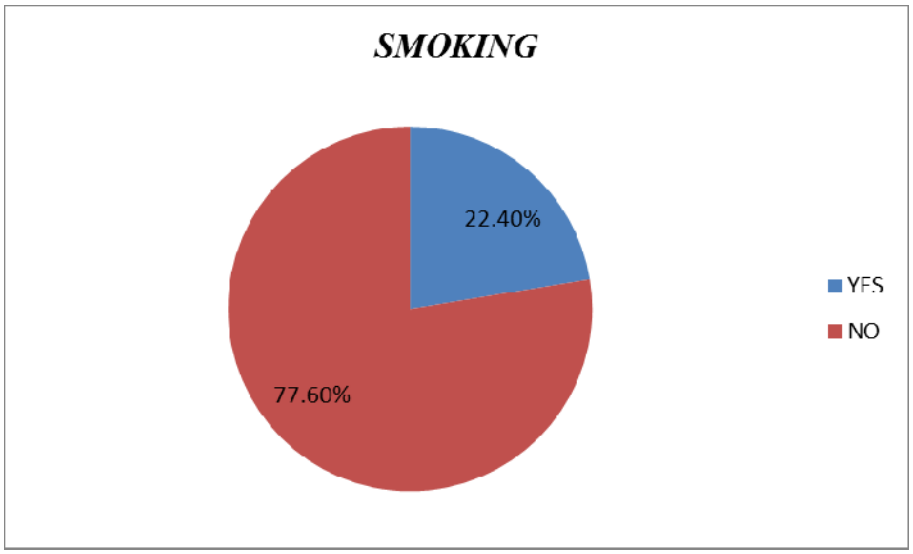


Figure.6: Smokers and Non-smokers in hypercholestrolemia

Table 7: Exercise

Exercise	Number of patients
yes	59(60.2%)
no	39(39.8%)

Those who do regular exercise 59(60.2%) and those who do not do exercise 39(39.8%). More number of patients was do regular exercise compare to other. For exercise, at least 30 min/d of moderate-to-vigorous intensity was considered low risk, on the basis of current guidelines.25 Optimal body weight was defined as a BMI of _25 kg/m2, the standard World Health Organization cutoff for healthy weight.(Stephanie E. Chiuve,et.al.,2006)

Table 8: Sleep

Sleep	Number of patients
Normal	79(80.6%)
Decreased	18(18.4%)
Missing	1(1.0%)

Data were not available regarding counseling for smoking cessation. HRQOL was measured by questions ascertaining overall health status and the number of the preceding 30 days when physical health was not good, mental health was not good, and the person could not carry out usual activities because of poor physical or mental health. Kurt J. (Greenlund, PhD.,et.al.,2009)

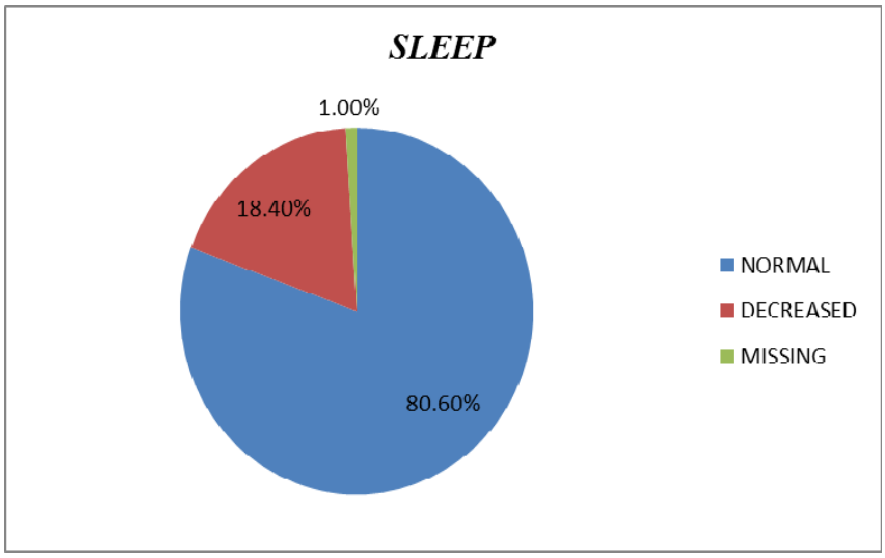
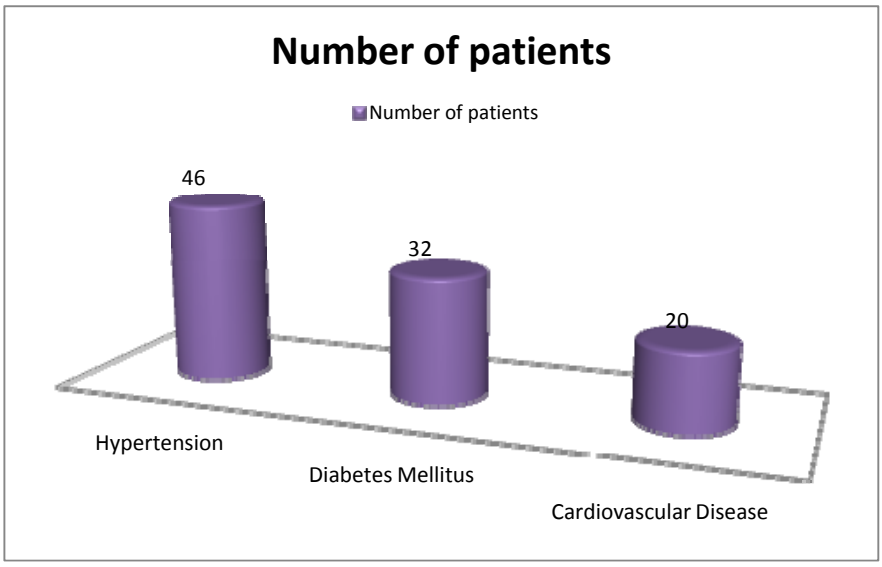


Figure.8; Sleeping Quality in hypercholestrolemia patients

Normal sleeping patients are 78(80.6%) as the same time 18(18.4%) patients are decreased sleeping. More patients are normal sleeping.

Table 9. Disease Status

Disease status	Number of patients
Hypertension	46
Diabetes Mellitus	32
Cardiovascular Disease	20



Figure,9: Disease status in Hypercholesterolemia patients

According to our study,maximum number of disease status patients are having hypertension. Then disease status in Diabetes mellitus. Compare to both disease status such as Hypertension,Diabetes Mellitus,Coronary heart disease is less.

Table: 10 Differentiation of Body Mass Index

Characteristics of the patients	Number of patients	BODY MASS INDEX		
		18-20	21-24	27-27
Hypertension with Hypercholesterolemia	36	12	11	7
Diabetes Mellitus with Hypercholesterolemia	32	8	17	8
Cardiovascular Diseases	14	3	8	3
Hypercholesterolemia	16	6	8	2

In this study,characteristics of patients are categorized into 4 groups.Out of 98 patients, 36 patients who are suffering from hypertension with hypercholesterolemia and 32 patients are affected diabetes mellitus with hypertension.From patients out of 14 patients having Cardiovascular disease with hypercholesterolemia. Hypercholestrolemia is a asymptomatic factor in this study.from this study,only 16 patients are affecting hypercholesterolemia. Persons with a body mass index _30.0 kg/m2 on the basis of reported height and weight were considered obese. (Kurt J. Greenlund, PhD.et.al.,2011)

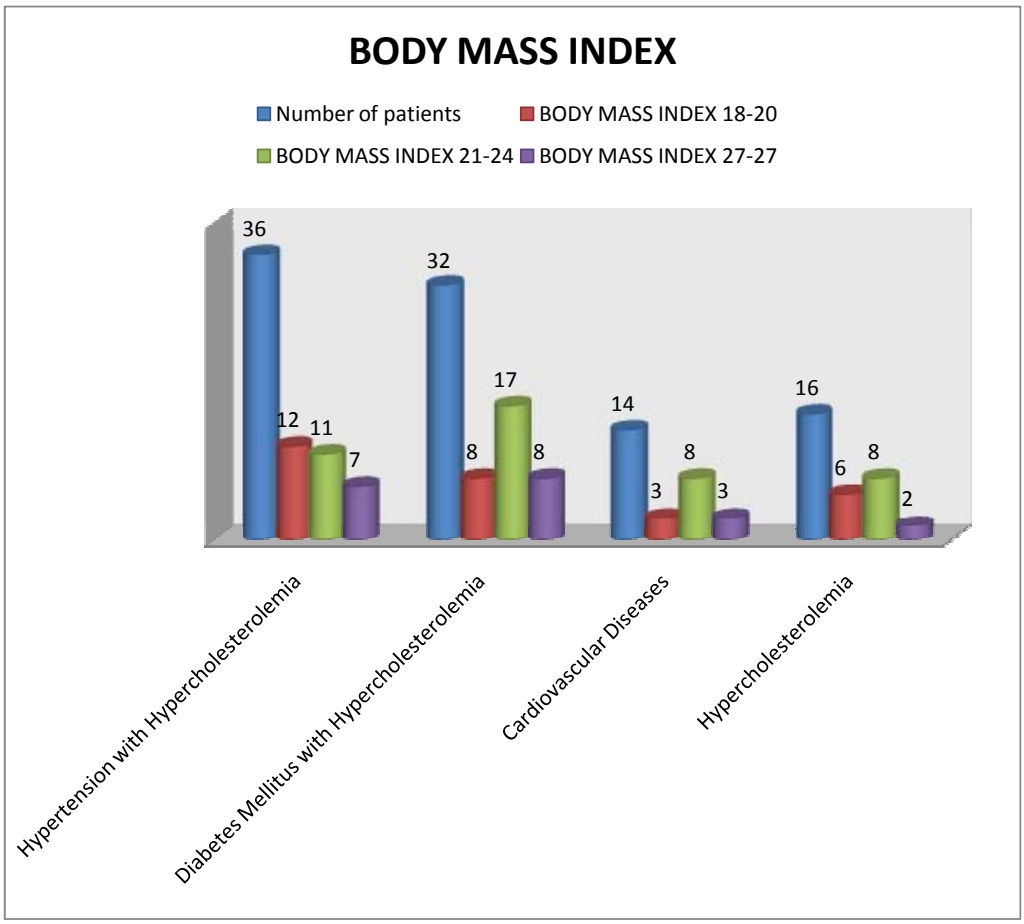


Figure.10: Differentation characteristics in Body Mass Index

Table 11:Differentation of Characteristics of social habits

Characteristics of the patients	Number of patients	Smoking		Alcohol	
		YES	NO	YES	NO
Hypertension with Hypercholesterolemia	36	11	18	8	26
Diabetes mellitus with Hypercholesterolemia	32	6	17	3	27
Cardiovascular Disease with Hypercholesterolemia	14	3	26	2	20
Hypercholesterolemia	16	2	15	1	16

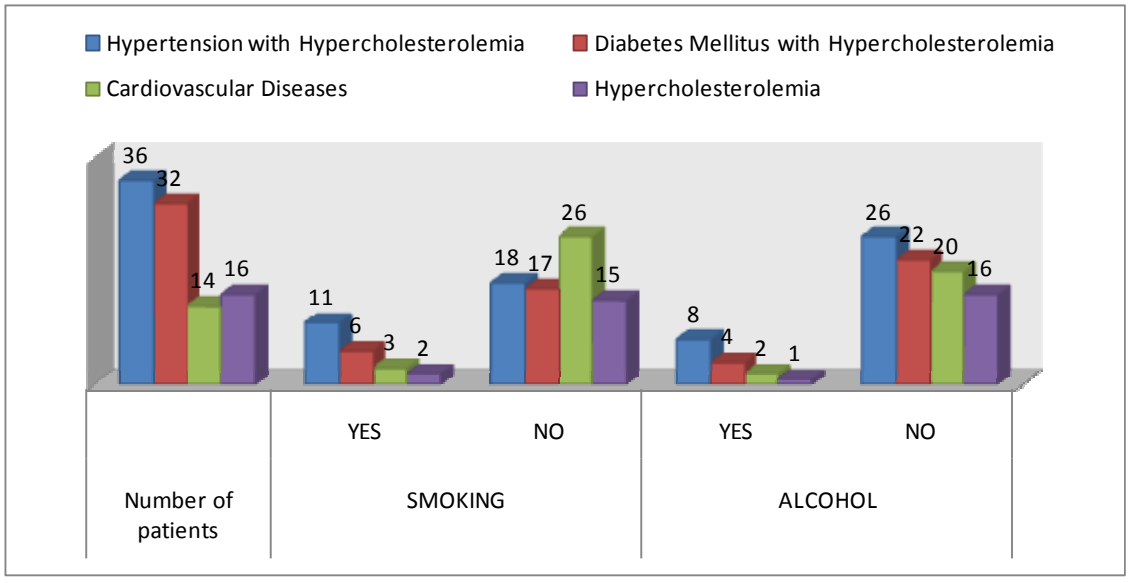


Figure.11:Differentiation characteristics of social habits

Patients those who are more affecting hypercholesterolemia with hypertension, the BMI ranges between underweight 16-20.In underweight category,12 patients are included. Hypertension with hypercholesterolemia is more than compare to the other underweight category. Very less patients are included in cardiovascular disease with hypercholesterolemia.

Next category in between 20-24, more number of patients who are affected diabetes mellitus and hypercholesterolemia, just below diabetes mellitus with hypercholesterolemia more number in hypertension with hypercholesterolemia BMI range between 20-24 hypercholesterolemia with cardiovascular disease is very less.

Table.12:Laboratory Data Determinations

Lab Datas	Normal values (mg/dl)	Hypercholestrolemia (no.of patients)	Hypertension with Hypercholestrolemia(No of patients)	Diabetes mellitus with Hypercholestrolemia (No of ptnt)	Cardiovascular disease with Hypercholestrolemia (No of patients)
Total cholesterol	<150	6	13	12	8
	>200	10	23	20	6
TG	60 - 170	4	15	17	4
	170- 250	12	21	15	12
HDL	>30	5	16	15	6
	<30	11	20	17	8
LDL	<100	7	15	9	2
	>100	9	21	23	12
FBS	<125	14	28	7	5
	>125	2	8	25	9

Elevated total serum cholesterol is one of the modifiable risk factors of cardiovascular disease**,** Chih-Hsueh Lin,et.,al.1999.

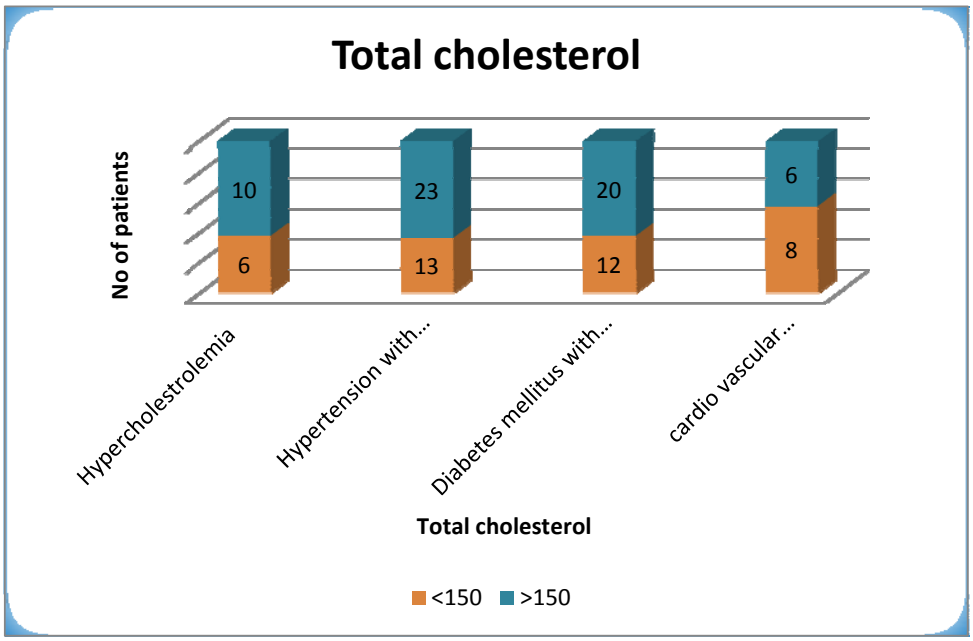


Figure 12(a): Clinical laboratory value of Total cholestrol

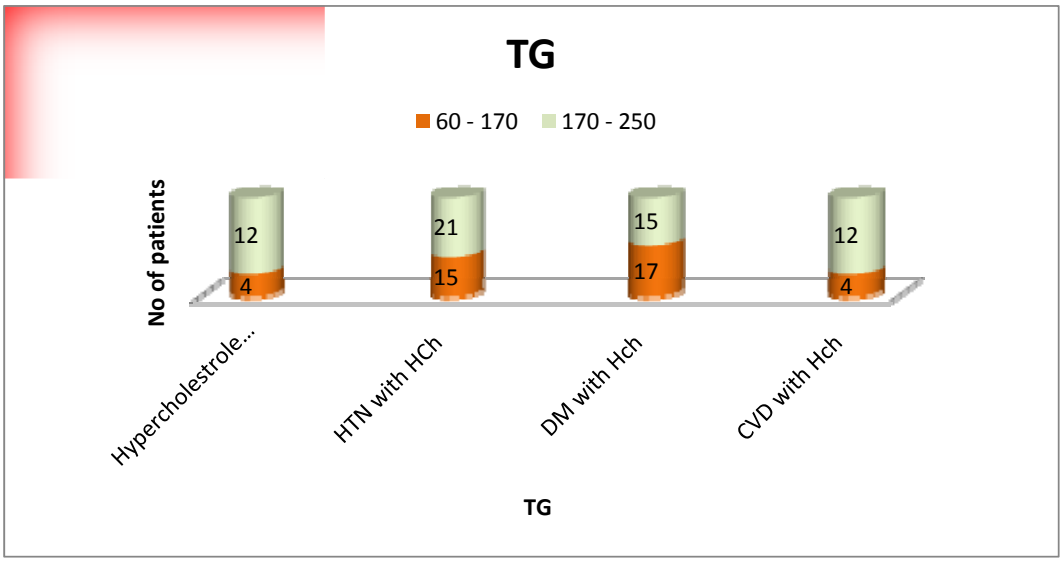


Figure 12(b):Clinical laboratory value of Triglycerides

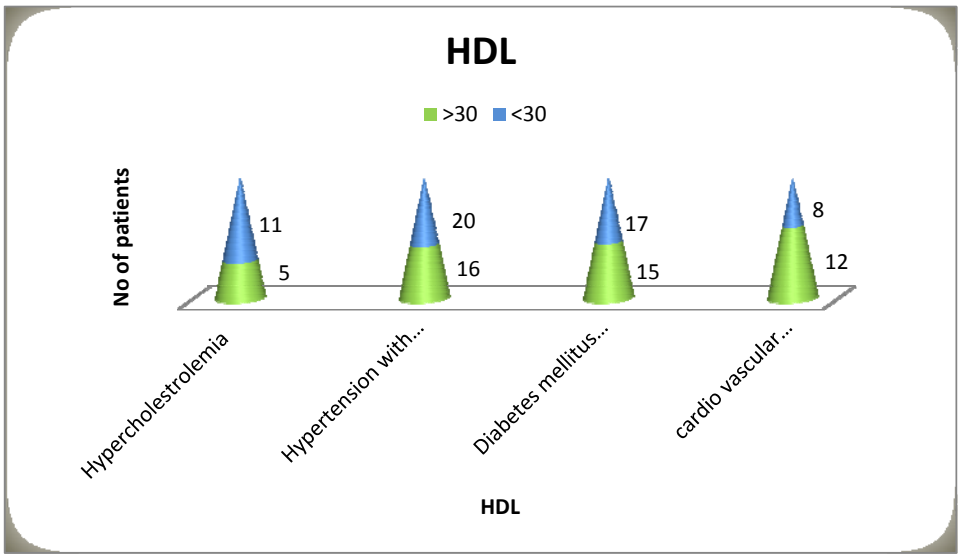


Figure 12.(c): Clinical laboratory value of HDL

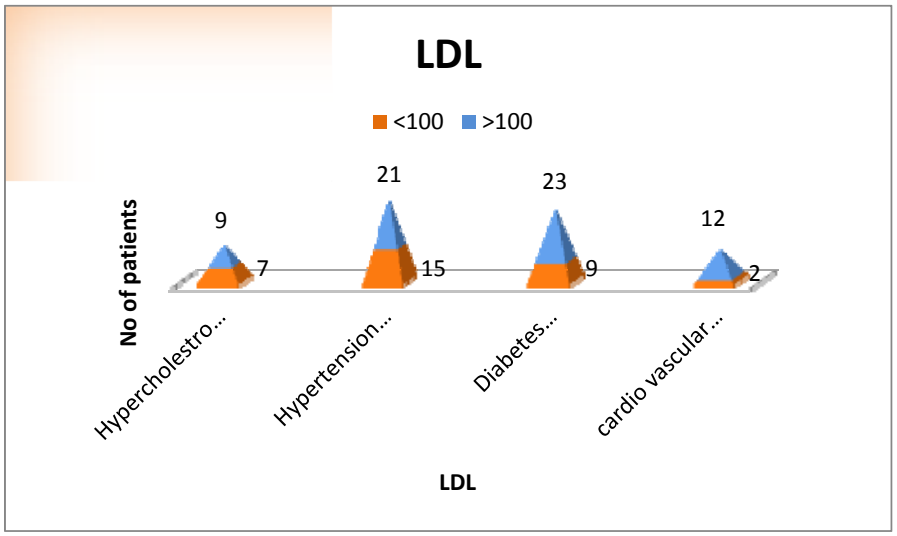


Figure 13.(d):Clinical laboratory value of LDL

The disorder is caused by mutations in the gene that encodes the low density lipoprotein cholesterol (LDL-C) levels. The best predictor of LDL-C goal attainment was the use of combined therapy with statin and ezetimibe.(Nelva Mata.et.al.,2011)

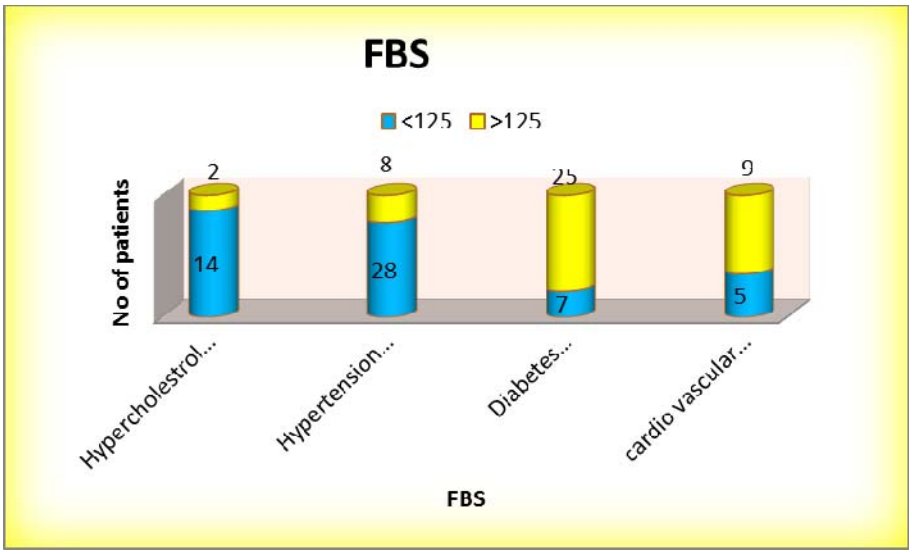


Figure.12(e): cClinical laboratory value of FBS

The distinction between co-morbidities and complications of diabetes was based on medical records of the patient. Diabetic patients living in the Gaza strip camps have a poor HRQOL compared to non-diabetic controls living under the same conditions and diabetic patients surveyed in other studies. (Ashraf Eljedi,et.al.,2006)

Among this study, from clinical profiles, is divided into 5 category. In this category total cholesterol is more in hypertension with hypercholesterolemia. Less number of total cholesterol in hypercholesterolemia.

Triglyceride is the second category. From the second category most of the patients with normal level of triglyceride level are found in diabetes mellitus with hypercholesterolemia patients. From the high triglyceride levels are more in hypertension with hypercholesterolemia.

High density lipoprotein is the next category, from this category most of the patients with normal level of HDL level are found in hypercholesterolemia patients. Less amount of HDL are found in cardiovascular disease with hypercholesterolemia.

In Low density lipoprotein category,most of the patients with normal level of LDL are found in hypertension with hypercholestrolemia and more amount of LDL level are found in diabetes mellitus with hypercholestrolemia.

Fasting blood sugar level is the next category,in this category most of the patients are normal level of blood sugar in hypertension with hypercholestrolemia.More number of pateints are more FBS levels in diabetes mellitus with hypercholestrolemia.

Table 13.Frequency of Reported Health

Reported Health	Number of patients
+	13(13.3%)
++	1(1.0%)
_	38(38.8%)
__	7(7.1%)
0	37(37.8%)
Missing	2(2.0%)

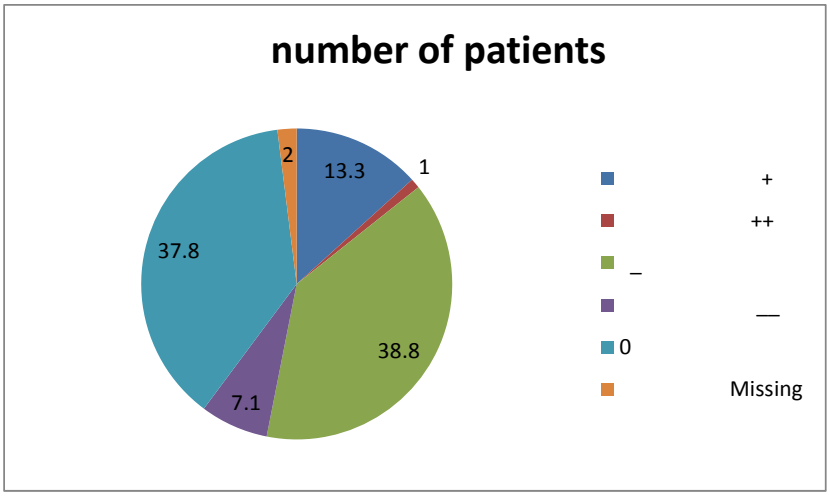


Figure 13: Frequency of Reported Health

In frequency Reported Health 13(13.3%) patients are better health and 1(1.0%) patients are having better health.

Out of 98 patients, frequency of reported health 38(38.8%) patients is having worse health and 7(7.1%) patients are having worse health condition. In frequency of reported health 37(37.8%) patients are having very worse health conditions. In frequency of reported health 2(2.0%) patients are missing from this data.

Table 14.Quality of life Scores

Scale	Item	Mean(SD)
Physical Functioning(PF)	3a. vigorous activities, such as running, lifting heavy objects, or participating in strenuous sports. 3b . Moderate activities, such as moving table, pushing a vaccum cleaner,bowling,or playing golf 3c. Lifting or carrying groceries 3d. Climbing several flights of stairs 3e. climbing one flight of stairs 3f. Bending,Kneeling,or Stooping 3g. Walking more than a mile 3H. Walking several hundred yards 3i. Walking 100 yards 3j. Bathing or dressing oneself	47.23
Bodily Pain (BP)	7. Intensity of bodily pain 8. Extent pain interfered with normal work.	46.02
General Health (GH)	1.isyour health: excellent, Very good, good, fair or poor. 11 a. seem to get sick a little easier than other people. 11 b. as healthy anybody I know. 11 c. expect my health to get worse. 11 health is excellent	44.41

Vitality (V)	9a.feel full of life. 9e.have a lot of energy 9g.feel worn out 9i.feel tired	48.66
Socialfunctioning (SF)	6. extend health problems interfered with normal social activites. 10.frequency health problems interfered with social activities.	44.01
Role-Emotional	5a.cut down the amount of time spent on work or other activites. 5b.accomplished less than you would like. 5c.did work or other activites less carefully than usual.	44.30
Mental Health	9b.be very nervous. 9c.felt so dull in the dumps that nothing could cheer you up. 9d.Felt carm and peaceful. 9F.Felt down hearted and depressed .9h.been happy	51.43
Physical Component Summary	a) Physical Functioning b) Role-Physical c) Bodily Pain d) General Health	73.38
Mental Component summary	a) Vitality b) Social Functioning c) Role Emotional d) Mental Health	71.73
Total quality of life score	79.62	

From scores, total quality of life score is more. Physical component summary, mental component summary are in same category. Moderate quality of life score in mental health. Physical Functioning, Social Functioning, Role emotional, Bodily pain, Vitality and general health in low quality of life scores.

The Short Form-36 (SF-36) Health Survey, version 2.0 [21] was used to assess HRQOL. Its validity, reproducibility and responsiveness to change over time have been well demonstrated . It has 36 items that measures the health concepts of physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality, social function, role limitations due to emotional problems, and mental health. It also contains a single item that examines change in health over time. Summary measures of physical health (Physical Component Summary [PCS]), mental health (Mental Component Summary [MCS]) and Total QOL score (T-score) were derived from the completed questionnaire.

Table 15:level of physical component summary

QoL Score	Percentage of patients
<60	20.4
60-70	16.3
70-80	29.6
>=80	33.7

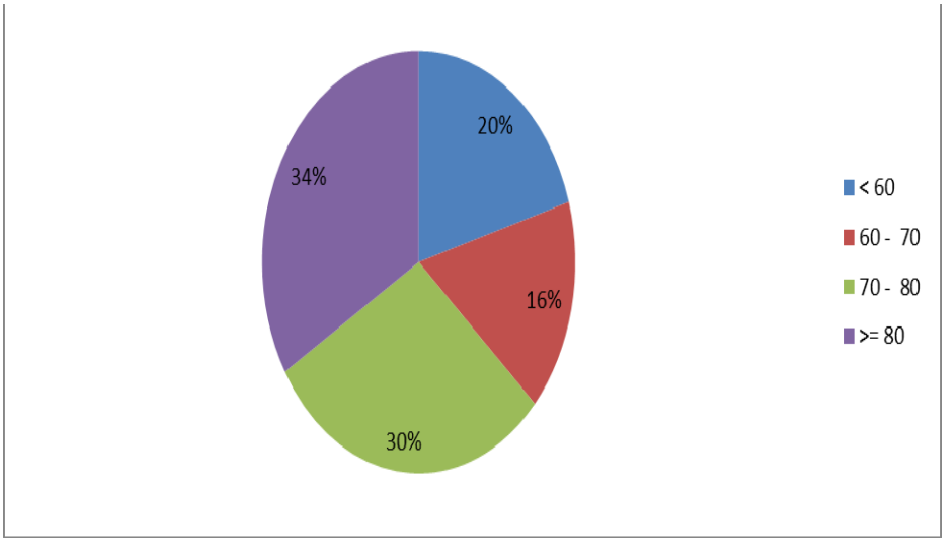


Figure 15. Level of Physical Component Summary

From this graph ,the level of physical component quality of life sore in <60,percentage of patients were 20.4 and quality of life score between 60-70,the percentage of patients were 16.3.Level of physical component quality of life between age 70-80,the percentage of patients were 29.6 and the quality of life score >=80,the percentage of patients 33.7.

Table 16: level of mental component

QoL Score	Percentage of patients
<60	22.4
60-70	23.5
70-80	25.5
>=80	28.6

Figure 16. Level of Mental Component Summary

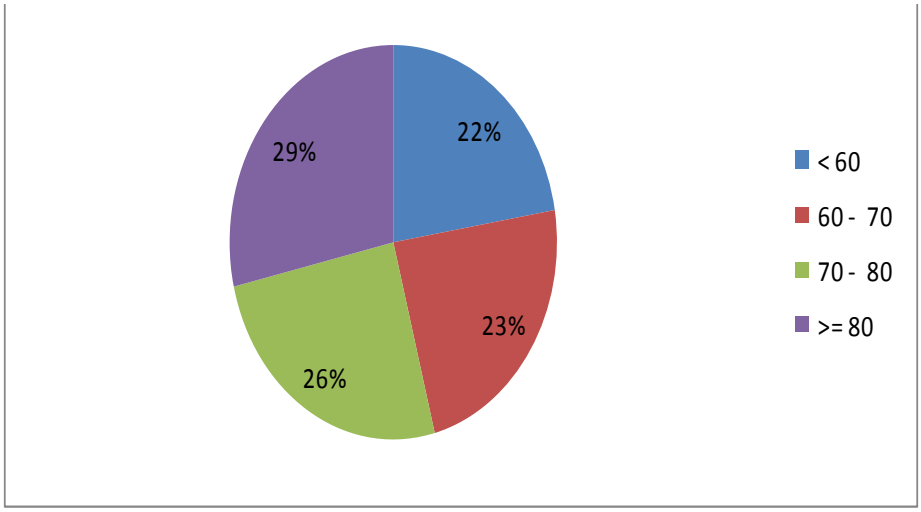


Figure 16. Level of Mental Component Summary

From the level of mental component ,the quality of life score <60,percentage of patients 22.4 and quality of life between 60-70 the percentage of patients 23.5.From this graph, the age group between 70-80 the percentage of patients 25.5% and quality of life >=80,the percentage of patients 28.6.

Table 17.level of combined QoL

QoL Score	Percentage of patients
<60	12.2
60-70	12.2
70-80	20.4
>=80	55.1

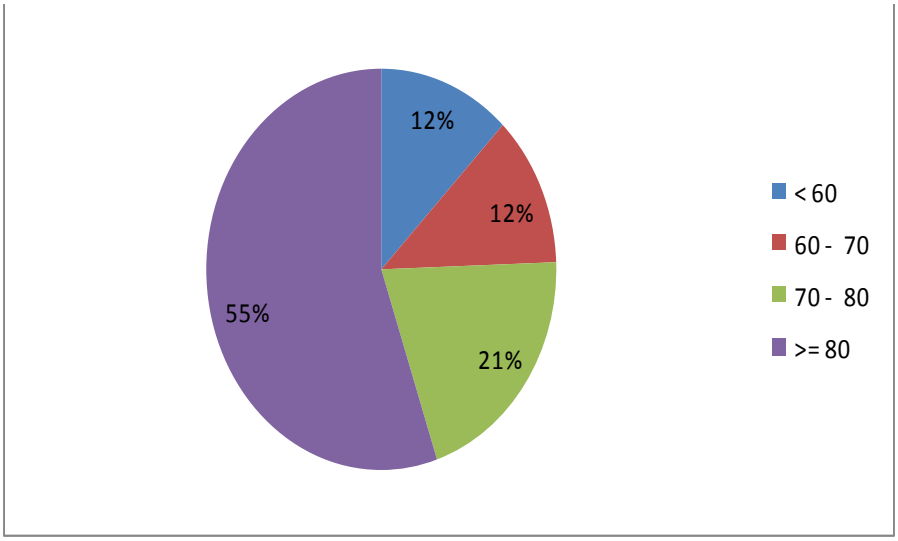


Figure 17.evel of combined QoL Score

From this graph, the level of combined quality of life score <60,the percentage of patients were 12.2 and quality of life between age group 60-70,the percentage of patients 12.2.Quality of life score between70-80,the percentage of patients were 20.4 and quality of life score >=80,the percentage of patients were 55.1

Table 18: Between-group differences in the quality of life score (mean+_SD) as a function of socio-demographic profiles.

Table18 (a): Quality of life score in socio-demographic profile in gender

Health domains	MALE	FEMALE
Physical Health	46.9±19.9	47.6±21.6
Role Function	48.9±19.1	44.6±19.1
Bodily Pain	44.8±12.4	47.4±16.3
General Health	45.1±11.6	43.7±11.6
Vitality	46.0±11.6	51.6±10.9**
Social Function	46.2±17.1	41.6±17.5
Role - Emotional	44.9±18.6	43.7±17.8
Mental Health	51.3±10.5	51.5±11.6
Quality of Life	82.5±19.6	76.3±15.8
Physical Component Summary	77.1±18.7	69.2±13.6
Mental Component Summary	73.5±16.4	69.8±15.9

(**indicates a significant association ($p<0.05$)

From this table, gender has a significant association between vitality in quality of life score in socio-demographic profile.

Table.18 (c) Quality of life score in socio-demographic profile age group

Health domain	30-69	70-89
Physical Health	44.9 ± 22.3	49.8 ± 18.6
Role Function	42.8 ± 19.5	51.4 ± 15.6
Bodily Pain	48.1 ± 14.9	43.8 ± 13.5
General Health	44.2 ± 10.3	44.6 ± 12.9
Vitality	49.3 ± 11.6	48.0 ± 11.6
Social Function	48.0 ± 17.6	39.6 ± 16.1
Role - Emotional	38.6 ± 18.3	50.5 ± 16.1
Mental Health	52.0 ± 10.4	50.9 ± 11.7
Quality of Life	77.7 ± 18.1	81.7 ± 18.0
Physical Component Summary	70.5 ± 17.6	76.4 ± 15.6
Mental Component Summary	71.1 ± 15.6	72.4 ± 17.0

From this table age group has a significant association with Role-physical, Social functioning and Role-Emotional scores.

Table18 (b) EDUCATION

Health Domains	literate	illiterate
Physical Health	46.4±20.6	55.6±21.9
Role Function	46.7±17.6	46.1±24.5
Bodily Pain	46.1±14.5	41.6±9.6
General Health	44.3±11.4	43.6±14.4
Vitality	48.5±11.6	47.7±10.0
Social Function	44.2±17.8	42.2±13.3
Physical Health	44.6±18.3	40.6±19.1
Role - Emotional	51.9±11.2	45.6±6.8
Mental Health	79.9±18.2	76.6±18.7
Quality of Life	73.3±17.2	74.0±15.3
Physical Component Summary	72.1±16.4	67.3±15.0

From this table, there is no significant difference between literate and illiterate quality of life.

Table 18(c): INCOME

Health Domain	<10000	10000-20000	>20000
Physical Health	43.8±17.5	47.2±21.6	47.8±19.2
Role Function	35.9±24.1	46.5±18.1	49.5±17.5
Bodily Pain	55.8±16.8	45.4±14.8	46.2±12.9
General Health	44.3±13.5	44.0±11.3	45.6±12.4
Vitality	48.4±3.1	49.2±12.2	47.5±11.0
Social Function	37.5±10.2	45.3±18.9	41.7±13.4
Role - Emotional	35.4±22.9	44.2±18.6	46.0±16.7
Mental Health	53.8±8.5	52.0±11.4	49.6±10.6
Quality of Life	86.0±25.5	80.4±18.5	76.9±16.0
Physical Component Summary	68.3±15.9	74.1±17.7	72.3±15.2
Mental Component Summary	74.3±28.3	73.2±16.4	67.7±13.4

From this table, there is no significant association between income in quality of life score.

Table 19.Between –group differences in the quality of life score (mean+_SD) as a function of clinical profiles.

Alcoholic

Table 19 (a): QUALITY OF LIFE SCORES IN ALCOHOLIC

Health Domain	Alcoholic	Non-alcoholic
Physical Health	60.0±14.8*	45.1±20.8*
Role Function	46.9±17.5	46.9±18.4
Bodily Pain	41.0±14.3	46.9±14.3
General Health	48.8±8.3	43.7±11.9
Vitality	45.5±11.6	49.2±11.6
Social Function	45.5±21.1	43.8±16.7
Role - Emotional	44.0±17.4	44.3±18.4
Mental Health	57.5±9.6*	50.4±11.0*
Quality of Life	74.2±15.4	80.5±18.4
Physical Component Summary	69.3±15.0	74.1±17.1
Mental Component Summary	66.2±12.7	72.7±16.6

This group differences in the quality of life score in alcohol as a function of clinical profiles, mainly explained about 11 scores. Alcohol habit has a significant association with mental health and physical functioning scores.

Excercise

Table:19(b):Quality of life score in Exercise

Health Domain	Regular exercise	Irregular exercise
Physical Functioning	46.6±21.6	48.2±19.3
Role-physical	46.2±18.9	47.9±17.3
Bodily Pain	45.1±15.3	47.4±12.9
General Health	43.7±12.8	45.5±9.6
Vitality	49.4±11.5	47.6±11.8
Social-Functioning	45.8 ±18.4	41.3±15.5
Role-Emotional	44.2±19.1	44.4±16.9
Mental Health	50.4±9.9	52.9±12.5
Quality of life	78.1±18.3	81.9±17.6
Physical component summary	71.4±17.0	76.4±16.5
Mental Component summary	71.3±16.5	72.3±15.9

The quality of life score, there is no significant association between the quality of life score in exercise.

Food habits

Table 19© :Quality of life style in Food habits

Health Domain	Veg	Non-veg	Both
Physical Health	47.1±15.7	45.7±21.6	50.3±20.8
Role Function	43.8±9.2	45.9±20.7	50.2±15.4
Bodily Pain	48.3±13.6	46.1±14.2	44.9±15.3
General Health	46.3 ± 9.5	44.9 ± 11.9	42.7 ± 12.0
Vitality	53.1 ± 10.5	47.8 ± 11.8	48.5 ± 11.5
Social Function	42.7 ± 13.5	43.9 ± 17.7	44.8 ± 18.5
Role - Emotional	46.5 ± 11.5	42.8 ± 20.7	46.3 ± 15.0
Mental Health	46.7 ± 12.7	52.0 ± 11.1	52.2 ± 10.0
Quality of Life	79.3 ± 14.5	81.1 ± 20.6	76.9 ± 13.6
Physical Component Summary	72.3 ± 11.6	73.9 ± 19.2	72.9 ± 13.8
Mental Component Summary	70.2 ± 16.0	73.8 ± 17.6	68.3 ± 13.0

From this table there is no significant association between food habits in quality of life scores.

Sleep status

Table 19(d): Quality of life scores in sleep status.

Health Domain	Normal	Decreased
Physical Health	46.5 ± 21.1	48.8 ± 17.8
Role Function	47.1 ± 18.1	47.6 ± 18.1
Bodily Pain	45.3 ± 13.6	50.1 ± 17.3
General Health	44.0 ± 12.1	46.3 ± 9.6
Vitality	48.3 ± 12.0	50.0 ± 9.6
Social Function	43.4 ± 16.6	47.9 ± 20.2
Role - Emotional	43.6 ± 18.6	47.2 ± 16.9
Mental Health	50.9 ± 11.2	53.3 ± 10.3
Quality of Life	79.2 ± 19.4	82.2 ± 11.0
Physical Component Summary	72.7 ± 17.9	77.3 ± 10.6
Mental Component Summary	72.2 ± 17.3	69.5 ± 10.8

From this table, there is no significant association between sleep status in quality of life scores.

SMOKING

Among the variables analyzed, smoking has a significant association with mental health score in quality of life score.

Table 19(f): Quality of life scores in socio-demographic data in smoking

Health Domain	Smoker	Non-smoker
Physical Health	44.1 ± 20.6	48.1 ± 20.7
Role Function	42.6 ± 16.7	48.1 ± 18.5
Bodily Pain	49.5 ± 14.0	45.0 ± 14.4
General Health	42.6 ± 10.0	44.9 ± 12.0
Vitality	46.3 ± 12.6	49.3 ± 11.3
Social Function	38.1 ± 15.2	45.7 ± 17.6
Role - Emotional	42.0 ± 14.0	45.0 ± 19.2
Mental Health	56.6 ± 9.4*	49.9 ± 11.0*
Quality of Life	83.1 ± 18.1	78.6 ± 18.0
Physical Component Summary	75.5 ± 18.6	72.8 ± 16.4
Mental Component Summary	74.6 ± 16.7	70.9 ± 16.1

DISCUSSION

6.1 General Observation

Hypercholesterolemia and its risk factors has become an major cause of illness and disability across the world. The number of people with hypercholesterolemia is increasing due to population growth, aging, urbanization and increasing prevalence of obesity and physical activity. In our present study 100 hypercholesterolemia patients were enrolled according to our own inclusion criteria. They were categorized according to sociodemographic, lifestyle and food habits.

Gender

In our study, more number of male patients compare to female.

Age

Among our study, age wise distribution is categories into five groups. In this group more number of patients between age 60-69.less number of patients in the age group 30-49.In moderate number of patients in 70-79 age group.50-59 category, number of patients is 15 and 80-89 age group number of patients is 12.

Education

In socio-demographic data's, more number of patients are secondary school level and less number of patients are in primary school. Moderate level of patients is in higher study.

Smoking

In our patients, more number of patients are less using tobacco. Cigarette smoking remains a cardiovascular risk factor. Patients who stop smoking can expect an increase of up to 30 percent in their HDL levels.

Alcohol

Among maximum number of patients are less taking alcohol.

Exercise

Among this study, more number of patients those taking regular exercise, compare to others. Physical inactivity is an independent risk factor, raising the risk of cardiovascular event twofold. Aerobic exercise raises HDL levels and lowers triglyceride levels. When it results in weight loss, it contributes to LDL reduction.

Sleep

In our study normal sleeping patients are more than less sleeping patients. Avoiding stress is another main risk factor in hypercholesterolemia.

Disease Status.

According to our study, maximum number of disease status patients are having hypertension. Then disease status in diabetes mellitus. Compare to both disease status such as hypertension,diabetes mellitus,cardiovascular disease is less. Disease status is the main risk factors.

Body mass index

In our present study,more number of patients is in normal category.Just below the normal category number of patients are obese.Body mass index in between normal and obesity have alittle range variation.Very less number of patients are in underweight category. Obesity is the main risk factor for hypercholesterolemia. Weight maintains is an important guideline for obesity. By replacing saturated fats is the main factor to cause over weight.

Differentiation of characteristics of patients.

In this study, characteristics of patients are categorized into four groups. Out of 98 patient.More number of patients who are suffering from hypertension and hypercholesterolemia. Then diabetes mellitus and hypercholesterolemia were secondly affecting factors. From patients having cardiovascular disease with hypercholesterolemia are in moderate factors. Hypercholesterolemia is a asymptomatic factor in this study. From this study, only less patients are affecting hypercholesterolemia.

BMI, is the main risk factor of hypercholesterolemia.BMI,≥ 25kg/m2 is considered as cardiometabolic risk factor.Base on the aforementioned risk factor definitions,individuals are considered to have cardiometabolic risk factor cluster if they had BMI ≥ 25kg/m2 and any two of the following risk factors:Hypertension,hyperlipidemia and diabetes.These factors was created for cardiometabolic risk factors.

BMI is categorized into three groups underweight between 18-20 and normal in between 20-24 and obesity 25-27.In this study most of the patients are under thr normal category, but only a little differences in between the normal group and obesity. Just below the normal group obese patients are more.

Patients those who are affecting hypercholesterolemia and hypertension,the BMI ranges between underweight 16-20.In this underweight category,12 patients are included.Hypertension with hypercholesterolemia is more than compare to the other underweight category.Very less patients are included in cardiovascular disease and hypercholesterolemia.

Next normal category in between 20-24,more number of patients who are affected diabetes mellitus and hypercholesterolemia and just below this category more number of patients in hypertension with hypercholesterolemia.In BMI range between 20-24 hypercholesterolemia and cardiovascular disease is very less in this category.

In BMI range between 25-27,total number of patients are 20.from this category,more number of patients are affecting diabetes mellitus and hypercholesterolemia.Then hypertension and hypercholesterolemia is the another one in this category,cardiovascular disease with hypercholesterolemia is very less compare to other.

Differentiation of characteristics of patients in social habits.

According to our study total number of patients are 22 and non-smoker are 76.The patients who are affecting hypertension with hypercholesterolemia are more

smokers and diabetes with hypercholesterolemia is in moderate range.Those who are having cardiovascular disease with hypercholesterolemia and hypercholesterolemia patients are very less smokers compare to others. Non-smokers are more than compare to smokers. In non-smoker group more number of non-smokers are in the cardiovascular disease with hypercholesterolemia group. Very less non-smoker patients in hypercholesterolemia.

Among our study population total number alcohol intake patients are 14 and non-alcoholic are 84.Compare to alcohol intake patients are less than non-alcohol group. In this study more number of patients are more number of patients are in hypertension with hypercholesterolemia and less number of patients in hypercholesterolemia group.In this study non-alcoholic patients are more in hypertension with hypercholesterolemia group less in diabetes mellitus with hypercholesterolemia.

Family history

Among our study population, more number of patients are having family history. Hypertension is the,main syndrome which is affecting more patients in family history.Diabetes mellitus is the secondly included in the family history,very less in cardiovascular disease.

Laboratory Data Determination

The distinction between co-morbidities and complications of diabetes was based on medical records of the patient. Diabetic patients living in the Gaza strip

camps have a poor HRQOL compared to non-diabetic controls living under the same conditions and diabetic patients surveyed in other studies.(Ashraf Eljedi,et.al.,2006)

Among this study, from clinical profiles, is divided into 5 category. In this category total cholesterol is more in hypertension with hypercholesterolemia. Less number of total cholesterol in hypercholesterolemia.

Triglyceride is the second category. From the second category most of the patients with normal level of triglyceride level are found in diabetes mellitus with hypercholesterolemia patients. From the high triglyceride levels are more in hypertension with hypercholesterolemia.

High density lipoprotein is the next category, from this category most of the patients with normal level of HDL level are found in hypercholesterolemia patients. Less amount of HDL are found in cardiovascular disease with hypercholesterolemia.

In Low density lipoprotein category,most of the patients with normal level of LDL are found in hypertension with hypercholestrolemia and more amount of LDL level are found in diabetes mellitus with hypercholestrolemia.

Fasting blood sugar level is the next category,in this category most of the patients are normal level of blood sugar in hypertension with hypercholestrolemia.More number of pateints are more FBS levels in diabetes mellitus with hypercholestrolemia.

Frequency Reported Health

In our patients, frequency reported health patients were better health and 1(1.0%) patients were better health. Outof 98 patients, frequency of reported health 38(38.8%) patients was having worse health and 7(7.1%) patients are having worse health condition. In frequency of reported health patients 37(37.8%) were having

very worse health conditions. In frequency of reported health 2(2.0%) patients were missing from this data.

Quality of life scores

Among our study,Physical functioning 10 items were included in physical functioning.

1) **Physical Functioning**

In physical functioning low scores indicate significant limitations in performing physical activities while high scores reflect little or no such limitations.According to our study,47.23 is the range in physical functioning. It means in physical functioning indicate significant limitations in performing physical activities.

2)Role-Physical

The 4-item RP scale covers ,an array of physical health-related role limitations.In our study RP,quality of life score is 43.25.It indicates low scores.low scores on RP scales reflect problems with work or other activites as a result of physical problem.

3) General Health

The general health scale consist of five items, including a rating of health(excellent or poor) and four items addressing the respondents view and expectations of his or her health. According to our study population, general health quality of life score is 44.41.It indicate low scores. In general health low scores indicate evaluation of general health as poor and likely to get worse.

4) Bodily Pain

The bodily pain scale comprises two items; one pertaining to the intensity of bodily pain and one measuring the extent of interference with normal work activites due to pain.In our patients, the quality of life score in BP is 46.02.It indicate low scores.In BP low scores indicate high levels of pain that impact normal activities.

5) Vitality

Vitality is a 4-item measurement (ie,energy level and fatigue) was developed to capture differences in subjective well-being.Among our study the quality of life score in vitality is 48.66.It indicate feelings of tiredness and being worn out.

6) Mental Health

Mental Health contain five main items.It includes one or more items from each of four major mental health dimensions.In our study,mental health scoring is high.It indicate feelings of peace,happiness and clam all or most of the time.The mental health,quality of lif score is 51.43.

7) Social functioning

SF,is a 2 item scale assess health related effects on quality and quantity of social activites.Here in our study,the quality of life score in SF is 44.30.It indicate lowest score.The lowest score indicate extreme or frequent interference with normal social activites due to physical and emotional problems.

8) Role- Emotional

The 3-item RE assess mental health related role limitation.Among our study, RE 44.30 is the quality of life score.Low scores on this scales reflect problems with work or other activites as a result of emotional problems.

Physical Component Summary and Mental component

Among to our study,Physical Component Summary the quality of life score is 73.38.In PCS measurement high score indicates little or no physical limitations,disabilities as decrements in well-being,a high energy level and good general health.

For Mental Component Summary,the quality of life score is 71.73.it means the MCS measures indicate high scores.A high score on the MCS measure indicates frequent positive effect,little or no psychological distress or limitations in usual social /role activites,due to emotional problems and good general health.

A strength of PCS and MCS measures in their value in distinguishing a physical health outcomes from a mental outcomes.

Level of physical Component Summary

In table 3a, level of physical component summary, quality of life of patients less than 60. At the same time quality of life of patient score between 60-70 is very low and the score between 70-80,the percentage of patients 29.6 %.Quality of life score is greater than or equal to 80,the percentage of patients 33.7 %.

Level of mental component summary

In the level of mental component summary, the quality of life scoring is less than 60,the percentage of patients 22.4%.Quality of life scoring between 60-70,the percentage of patients 23.5%. Quality of life scoring in between 7-80,25.5% of patients and quality of life scoring greater than or equal to 80,the percentage of patients 28.6%.

Level of combined QoL scores

In table 3c, level of combined QoLscore less than6, the percentage of patients is 12.2% and QOL scores in between 70-80,the percentage of patients 20.4%.As the same time ,QoL score greater than or equal to 80,the percentage of patients 55.1.

Between-group differences in the quality of life score (mean+_SD) as a function of socio-demographic profiles.

Gender

Of the total study population more number of malesare included in the quality of life scores. From the males, more number of quality of life score in Role-

physical, General-health, Social functioning, Role-motional, Total quality of life scores, Physical component summary and mental component summary. More number of quality of life score indicate that health is poor condition.

Of the total study population less number of females, more number of quality of life score in physical functioning, Bodily pain, Vitality, Mental health indicate the quality of life score health condition is poor.Role physical,General health, Social functioning,Role-Emotional,Quality of life scorephysical component summary and mental component summary are less quality of life score that indicate health is better.Gender has a significant association with VT score.

AGE GROUP:

Age group has a significant association with Role of Physical, Social Functioning and Role -Emotional in quality of life score.

EDUCATION

From education there is no significant association literate and illiterate in quality of life.However, physical function, bodily pain, mental health, mental component summary are higher in literate as compare to illiterate.

INCOME:

From income there is no significant association difference between income quality of life.

Between-group differences in quality of life score (mean+_SD) as a function of clinical profile.

Alcohol

Alcohol habit has a significant association with mental health and physical function scores. However physical function, Role-physical, General health, Vitality, social functioning, Mental health, are higher in those are not taking alcohol compare to alcohol consumption.

Body weight

From the quality of life score there is no significant association difference between body weight.

Execrise

From the quality of life score there is no significant association difference between exercise. However physical health, Role-physical, Bodily pain, General Health, Role-emotional, mental health, total Quality of life score, Physical component summary, mental component summary is higher than in non-alcohol consumption.

Food Habits

There is no significant association difference between food habits in the quality of life score.

Sleep status

From the quality of life score there is no significant association difference between sleep status.

Smoking

Smoking has a significant association with mental health in quality of life score.

Predictors of SF-36 component summary scores - Multivariate Regression Analyses reporting standardized beta

Multivariate analyses using multiple linear regression (stepwise selection) were performed to identify variables linked to QoL levels. The variables used are Age group, Gender, Marital Status, Education, Income, Food Habits, Body Weight and Sleep Status. Variable with p-value ≤ 0.15 entered in the model during stepwise regression. In the SF-36 model, the PCS and MCS scores were considered separate dependent variables.

A) Physical Component & Quality of Life

	Physical component summary (pcs)
	p-value
Age group	0.0440
Gender	0.0166
Sleep status	0.0957

Age group, Gender and Sleep Status are significantly associated with physical component scores.

Codes:

Age : 0 -age<67, 1-age>=67

Gender: 0-male , 1-female

Sleep : 0-normal, 1-decreased

B) Mental Component & Quality of Life factors

No Qol factors were significantly associated with Mental Components (Age group, Gender, Marital Status, Education, Income, Food Habits, Body Weight and Sleep Status – using step-wise regression)

CONCLUSION

According to our study from socio-demographic data, BMI, age group, disease status, family history are the main factors that increasing hypercholesterolemia and its risk factors. In quality of life score, our present study, reveals that gender, age, social functioning and Role-emotional has a strong association with mental health and alcohol consumption and smoking.Wereas ,no QoL factors were significantly associated with mental components (Age, Gender, Education, Income, Food Habits, Body weight and Sleep status).Total quality of life score, Physical component summary, mental component summary were high in quality of life score.

FUTURE RECOMMENDATION

Hypercholesterolemia, was the major contributors to atherosclerosis and coronary heart disease in our society.The National Institutes of Health, has created a set of guidelines that standardize the clinical assessment and management of hypercholesterolemia for practicing physicians , other professionals in the medical community.In addition, to modifying current strategies of risk assessment the new guidelines and stress the importance of an aggressive therapeutic approach in the management of hypercholesterolemia.The major risk factors, that modify low-density lipoprotein goals such as age,smoking,status,hypertensionhigh-densitylipoprotein levels, and high-density lipoprotein levels, and family history.The concept of "CHD equivalent"is introduced-conditions requiring the same vigilance used in patients with coronary heart disease.Patients with diabetes and those with a 10-year cardiac event risk of 20 percent or greater are considered CHD equivalents. Once LDL cholesterol was at an accepted level and physicians were advised to address metabolic syndrome, hypertriglyceima.

In our study,hypercholesterolemia may be induced due to lifestyle such as overweight, smoking and alcohol drinking and irregular exercise, uncontrolled diet .These risk factors were the major problems to increasing cholesterol.

Among this population more number of patients are affected hypercholesterolemia and its related related risk factors such as diabetes,hypertension,Coronary heart disease.Some patients are diabetes mellitus with hypercholesterolemia,diabetes with hypertension,hypercholesterolemia.In this case their quality of life style is very poor.

In our study quality of life style in health domain scores are higher.This means that the quality of life in hypercholesterolemia patient is poor.Physical inactivity and independent risk factor, raising the risk cardiovascular event.Aerobic exercise raises HDL level and lower triglyceride levels. Cigarette smoking remains a cardiovascular risk factor. Patients who stop smoking can expect an increase of upto 30% in their HDL level.

For future recommendation, like this study is mainly helpful to know the quality of life in health and help to reduce the poor health related quality of life. Health related quality of life study is mainly helpful to more aware about metabolic syndrome such as diabetes,hypertension and dyslipidemia.Some patients are not that much aware about this syndrome

In our population more number of peoples are affected the metabolic syndrome.The metabolic syndrome is increasing day by day.The health related quality of life survey is more helpful to the patients who are affected metabolic syndrome and future affecting patients.

In future,Health related quality of life study is more beneficial to new generation population. A wide range of study population needed in future study. Study population is more, and then we have to compare the quality of life scores in metabolic syndromes and quality of life scores in gender differences. This health related quality of life survey is help to improve the reduction of syndrome.

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PROFORMA

ASSESMENT OF HEALTH RELATED QUALITY OF LIFE IN SUBJECTS WITH HYPERCHOLESTROLEMIA

PATIENT DEMOGRAPHIC DATA

Patient Name : Date:

IP/OP no :

Age :

Sex :

wt./ ht :

BMI :

Marital Status :

CHIEF COMPLIANT

Primary Reason for Visit :

Duration of Presenting Symptoms :

PAST MEDICAL HISTORY

PAST MEDICATION HISTORY

FAMILY HISTORY

Presence of any disease :

Other family member with similar disease :

Yes ☐ No ☐

SOCIAL HISTORY

Level of education :

Economic status:

Diet : veg ☐ Non veg ☐

Habits : alcohol ☐ Tobacco ☐

Quality of sleep :

Exercise : Yes ☐ No ☐

DIAGNOSTIC TEST

Blood Pressure :

Lipid profile :

Cholesterol

Triglycerides

HDL (good cholesterol)

LDL (bad cholesterol)

Fasting blood Sugar level :

MANAGEMENT

DRUG NAME	DOSE	DURATION	FOLLOW UP				